

VISIONCARE'S IMPLANTABLE MINIATURE TELESCOPE (by Dr. Isaac Lipshitz)

**AN INTRAOCULAR TELESCOPE FOR TREATING
SEVERE TO PROFOUND VISION IMPAIRMENT DUE TO BILATERAL END-
STAGE AGE-RELATED MACULAR DEGENERATION**

PATIENT INFORMATION BOOKLET

IMPORTANT INFORMATION

This booklet will help you decide whether or not to have surgery to implant the Implantable Miniature Telescope (intraocular telescope) in your eye to reduce the effects of your vision impairment from age-related macular degeneration. Please read the whole booklet. Discuss it thoroughly with your eye doctor, your surgeon, your family and your friends until you get answers to all your questions. You need to understand the risks and benefits of implanting the intraocular telescope before you decide to have the surgery. You and your doctor must both complete the Acceptance of Risk and Informed Decision Agreement before you can have the surgery.

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GLOSSARY

Age-Related Macular Degeneration (AMD): an eye disease in older individuals that destroys sharp, central vision by damaging the retina. AMD makes it hard to read and recognize faces.

Bilateral AMD: AMD in both eyes.

Cataract: the natural lens of the eye becomes cloudy, causing hazy vision.

Central vision: ability to see “straight ahead” for reading, recognizing faces, or seeing details.

Contrast sensitivity: how well your eyes function in low light and how well you can distinguish one object from another or from the background.

Cornea: the clear front portion of the eye.

Corneal edema: swelling of the cornea that can make it cloudy and cause blurred vision.

Corneal endothelial cells: layer of cells on the inside of the cornea that keeps the cornea healthy and transparent by controlling the amount of fluid in it; if you lose too many corneal endothelial cells due to eye surgery or disease, your cornea can become cloudy and cause blurred vision.

Corneal transplant: replacement of your cornea with a new cornea from an organ donor.

Depth perception: the ability to see in three dimensions and to identify how far away an object is.

GLOSSARY (CONTINUED)

End-stage AMD: advanced AMD causing severe central vision loss that is not treatable by medication or laser surgery.

External telescope: a hand-held or externally worn telescope used to magnify objects.

Field of view: the angle of view from the center to the sides when looking forward, for example, 180 degrees of vision.

Implantable Miniature Telescope (“intraocular telescope”): a very small telescope that is surgically implanted in the eye after removing the natural lens. An intraocular telescope magnifies images and is intended to improve central vision in patients with end-stage AMD.

Intraocular: inside the eye.

Intraocular lens (IOL): a very small lens implanted in the eye to replace a cloudy natural lens during cataract surgery.

Lens or Natural Lens: transparent structure inside the eye behind the iris that focuses light onto the retina to create an image.

Macula: the central part of the retina at the back of the eye that is responsible for central vision.

MR-Magnetic Resonance

Peripheral vision: vision outside the center of gaze, on the sides.

Profound vision impairment: vision 20/400 or worse.

GLOSSARY (CONTINUED)

Retina: the light sensitive inner layer of the eye that is responsible for sight.

Severe vision impairment: vision 20/160 to less than 20/400.

Visual acuity: a measure of how well someone can see, for example, 20/20 or 20/200.

Wet AMD: abnormal blood vessels under the retina that leak blood and fluid that cause damage to the retina.

INTRODUCTION

If you are thinking about having surgery to have the **Implantable Miniature Telescope** (by Dr. Isaac Lipshitz) also called the **intraocular telescope**, placed in your eye, please read this Patient Information Booklet carefully. You may want a friend or family member to read it to you. You may want to discuss it with your family and friends. You should ask questions of your eye doctor, your surgeon and the eye care professionals who work with your eye doctor and surgeon. Take all the time you need to thoroughly consider and understand the information and get all your questions answered.

The intraocular telescope has potential benefits and potential risks. Only you can decide whether intraocular telescope surgery is a good option for improving your vision.

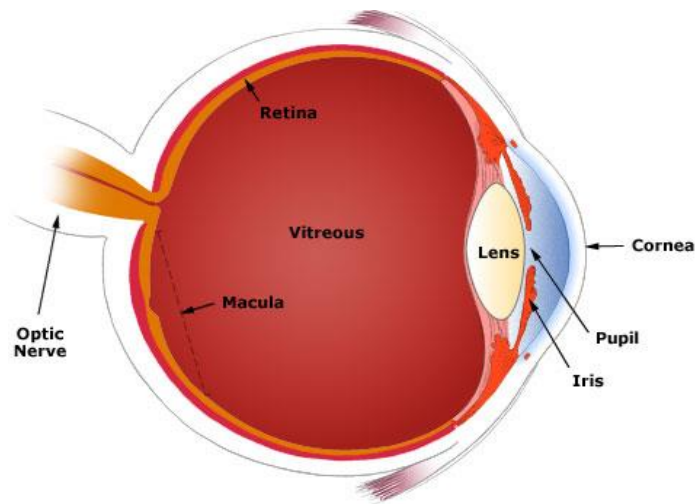
Information about the Eye and Age-Related Macular Degeneration (AMD)

The eye acts like a camera to focus light from outside the eye to form images or pictures on the surface of the **retina**. Light enters the eye through the **cornea** and **lens** which focus the light onto the retina.

The **macula** is located in the center of the retina. The macula provides **central vision**. Central vision allows you to see objects clearly and to do common daily tasks such as reading and recognizing faces.

AMD is a disease related to aging that gradually destroys the macula and therefore central vision. Figure 1 shows a picture of the inside of the eye.

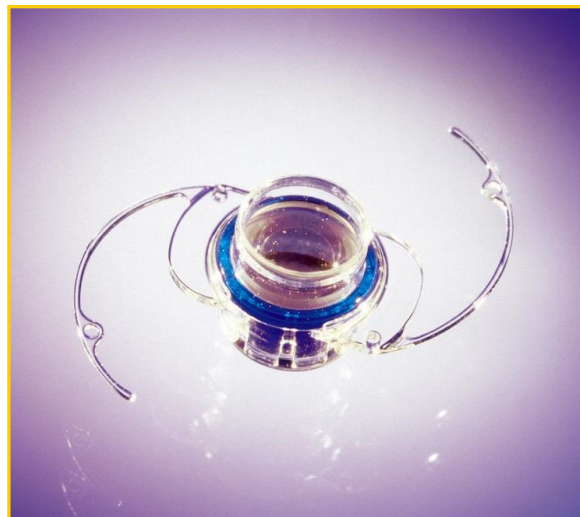
FIGURE 1
CROSS SECTION OF THE EYE



What Does the Intraocular Telescope Do?

The intraocular telescope is intended to improve distance and near vision in people who have lost central vision in both eyes because of **end-stage AMD**. The intraocular telescope is about the size of a pea and is surgically placed inside one eye. The implanted eye provides central vision. The other eye provides **peripheral vision**. A picture of the intraocular telescope is shown in Figure 2.

FIGURE 2: IMPLANTABLE MINIATURE TELESCOPE (by Dr. Isaac Lipshitz)



How Does the Intraocular Telescope Work?

When implanted in your eye, the intraocular telescope magnifies images and projects them onto a part of your retina that is healthy and can still see images.

ARE YOU A CANDIDATE FOR THE INTRAOCULAR TELESCOPE?

You are a candidate if you meet these criteria:

- You have end-stage AMD in both eyes.
- You are at least 75 years old.
- Your distance vision is no better than 20/160 but no worse than 20/800.
- You have cataract.
- You show improvement on an eye test chart using an **external telescope**.
- You agree to pre-surgery training with external telescopes with a **low vision specialist** long enough to make an informed decision.
- You agree to training with a low vision specialist after intraocular telescope surgery.
- You are informed of the intraocular telescope's risks and benefits.
- You understand and sign the Acceptance of Risk and Informed Decision Agreement for the intraocular telescope surgery.

ARE YOU SOMEONE WHO SHOULD NOT HAVE AN INTRAOCULAR TELESCOPE?

You should not have intraocular telescope surgery if:

- You have already had surgery in the same eye.
- You have poor peripheral vision in the other eye.
- You have uncontrolled glaucoma.

- You rub your eyes. Rubbing your eye after surgery could damage both the cornea and the intraocular telescope.
- Your eye doctor says you have a disease or condition that would make you a poor candidate.

You should discuss your medical and vision history completely with your eye doctor.

Only you, with the help of your eye doctor, surgeon, friends, and family, can decide whether to have the intraocular telescope implanted. If the potential benefits are more important to you than the risks, then you should ask your doctor if you are a good candidate for the intraocular telescope. If the risks seem greater to you than the potential benefits, you should let your doctor know that you do not want to have an intraocular telescope.

CLINICAL STUDIES

The following sections (What are the Risks of The Intraocular Telescope and What are the Benefits of the Intraocular Telescope) give the results of clinical studies of the intraocular telescope. 217 patients with vision impairment due to end-stage AMD in both eyes were studied at 28 U.S. centers to evaluate the safety and effectiveness of the intraocular telescope. Patients averaged 76 years of age, about half were female and half were male, and most were Caucasian.

WHAT ARE THE RISKS OF THE INTRAOCULAR TELESCOPE?

This section talks about the risks of having intraocular telescope surgery and about the risks of having the intraocular telescope during the 5 years after surgery. There may be other risks that were not detected in the studies, and the long-term risks of having the intraocular telescope more than 5 years are unknown.

Surgery. After surgery has started, your surgeon may not be able to implant the intraocular telescope. If this happens, an **intraocular lens (IOL)** will be implanted instead. You will have all the risks of the surgery but without any of the benefits of the intraocular telescope. About 5% (1 out of 20) of patients had this problem.

Corneal Edema. You may develop corneal edema, which is swelling of the cornea. Intraocular telescope surgery will cause you to lose some **corneal endothelial cells** immediately, and afterward you will continue to lose more cells over time than normally happens with aging. Once you lose corneal endothelial cells, they do not grow back.

During the 5-year period after intraocular telescope surgery, about 12% of patients had very low corneal endothelial cell density, which can cause corneal edema to develop. Corneal edema is usually not painful except in very severe cases. If corneal edema is persistent (does not go away) and becomes bad enough to impair your vision, you may need a **corneal transplant**. It may also be necessary to remove the intraocular telescope during the corneal transplant surgery.

Persistent corneal edema and persistent vision-impairing corneal edema are serious conditions that do not get better over time. Implanting the intraocular telescope in your eye will increase your risk of getting persistent corneal edema, which can progress to persistent vision-impairing corneal edema or the need for a corneal transplant. The risks of these events reported over a 5-year period of time are shown in Table 1.

**TABLE 1
RISK OVER 5 YEARS**

Persistent Corneal Edema	Persistent Vision-Impairing Corneal Edema	Corneal Transplant
9%	7%	4%

Vision Loss. Your vision may get worse. The risk of losing more than 2 lines of vision on the eye chart was about 12% over the 5 years following intraocular telescope surgery. Also, 48% of patients in the study reported that their vision-related quality of life either stayed the same or got worse after intraocular telescope surgery.

Removing the Intraocular Telescope. If you are unhappy with your vision after intraocular telescope surgery, you may want to have your eye surgeon remove the intraocular telescope. This requires another surgery with risks that are at least as high as the risks of the surgery to implant the intraocular telescope. The surgery to remove the intraocular telescope may cause additional loss of corneal endothelial cells, which may lead to **corneal edema**. During the 5-year period after intraocular telescope surgery, about 4% of patients had their intraocular telescope removed and replaced with an intraocular lens.

Some Other Risks of Intraocular Telescope Surgery:

- double vision
- inability or difficulty controlling when to switch from using one eye to the other
- decreased **peripheral vision** in the eye with the intraocular telescope
- bleeding in the eye due to surgery

- infection inside the eye
- decrease in **contrast sensitivity**
- the need to surgically remove the intraocular telescope if it breaks inside your eye
- medical or visual complications
- dizziness or a queasy feeling
- changes in **depth perception**
- difficulty seeing in dim light
- difficulty seeing in bright light
- cloudy or blurred vision that makes it hard to see
- difference in speed of motion of the images in the two eyes, when the eyes are moved together.

If you have intraocular telescope surgery, you should have a complete annual eye examination that includes checking your corneal endothelial cells. The annual examination will help you know whether any of the risks discussed in this section are happening to you.

WHAT ARE THE BENEFITS OF THE INTRAOCULAR TELESCOPE?

This section talks about the potential benefits of having intraocular telescope surgery.

The intraocular telescope may improve your vision (the ability to see) and may improve your vision-related quality of life.

Vision Improvement. Most patients implanted with the intraocular telescope had significant improvement in vision. At 1 and 2 years after surgery, about 75% of patients had an improvement in their distance visual acuity of 2-lines or more on the eye chart. A 2-line improvement would be from 20/200 to 20/125 or from 20/400 to 20/250.

About 60% of patients improved their distance vision by 3-lines or more on the eye chart. About 40% of patients improved their vision by 4-lines or more. Improvements in distance and near vision were similar.

There was a slight decline in visual acuity at 3 and 4 years after surgery. However, improvements in vision after intraocular telescope surgery are generally retained over time. Results beyond 5 years are unknown.

Vision-Related Quality of Life Improvement. The majority (52%) of patients implanted with the intraocular telescope reported improvement in their vision-related quality of life. This means that they were more able to carry out activities that required distance or near vision. It also means they were more able to take part in social activities, and to independently carry out the activities of daily life.

Other benefits include: Eye movements are normal with the intraocular telescope. Because the intraocular telescope is implanted inside your eye, whatever you are looking at can be followed with natural eye movements rather than by turning your head.

What Other Questions Should You Consider before Intraocular Telescope Surgery?

Is There a Way to See What Your Vision Will Be Like With the Intraocular Telescope Before the Surgery to Help You to Decide if the Intraocular Telescope May Work for You?

Yes. Before you decide whether to have intraocular telescope surgery, you will meet with low vision specialists to use an external telescope to see if your vision improves when using the external telescope. Using the external telescope will help you understand what it could be like to have an intraocular telescope in your eye. You will be asked to use the external telescope for as long as you need to see what the intraocular telescope will be like in your activities of daily living. You need to do this even if you have used external telescopes before. If you do not like your vision with the external telescope or your vision does not improve, you should not have the intraocular telescope implanted in your eye.

Your eye doctor will recommend low vision specialists to you. The low vision specialists will check your vision. They will show you how to use the external telescope and help you understand what your vision will be like with the intraocular telescope implanted in your eye. The specialists will work with you to see whether or not you are able to adjust to the magnification to improve your vision. They will discuss your functional goals (what you want to be able to do) and evaluate them with you. Most people will need 2 to 4 meetings with the low vision specialists. The meetings will be about thirty minutes to an hour long.

The external telescope will only determine if you will respond to magnification. Your ability to use the external telescope does not guarantee that you will be able to successfully use the intraocular telescope.

Will You Need Training to Learn How to Use Your Intraocular Telescope?

Yes. After you have surgery to implant your intraocular telescope, you will need to attend several training sessions with low vision specialists. The specialists will create a plan of care for you based on your individual situation and functional goals. The low vision specialists will work with you to teach you how to do your daily activities with your new intraocular telescope. Visits with the low vision specialists are important to getting the most benefit from your intraocular telescope. Each session will be thirty minutes to one hour long.

Are There Other Options You Could Use Instead of the Intraocular Telescope?

Yes. You can use handheld external telescopes, spectacle-mounted telescopes, or special magnifying eyeglasses instead of the intraocular telescope. You should discuss these options with your doctor.

What About Lucentis[®] and Other Drugs? Can You Use Them Instead?

No. Lucentis[®] is a medication used for earlier stages of AMD, called **wet AMD**. It is not used for your stage of AMD, which is called “end-stage” AMD. The intraocular telescope is intended to be used when Lucentis[®] is no longer effective.

WHAT TO EXPECT WITH THE SURGICAL PROCEDURE?

Before the Surgery

Before the surgery, your surgeon will get your medical history and check the health of both of your eyes.

Tell your surgeon if you take any medication or have any allergies. Be sure to discuss all your questions with your surgeon before scheduling your surgery. Ask your surgeon if you should

eat or drink right before the surgery. You should arrange for transportation to and from where you live.

The Day of Surgery

Surgery will be performed in an outpatient surgical setting. You should plan on 2 to 3 hours for surgical preparation, the surgery, and recovery period. You will remain awake during surgery. Your eye will be numbed at the beginning of the surgery so you will not feel any pain. You will get special eye drops to enlarge the pupil. Your eye will be held open with a special instrument, and an operating microscope will be placed in front of your eye. Your eye's **natural lens** will be removed. The intraocular telescope will then be implanted inside your eye in the same position where the natural lens was. The numbness will wear off after surgery.

If your surgeon is unable to implant the intraocular telescope during surgery, your surgeon will implant an intraocular lens (IOL).

After the Surgery

After the intraocular telescope is implanted you will be provided with several types of eye drops to use at home. These eye drops will prevent infection and reduce redness, burning and swelling. You will be provided instructions on when to use the medications and how long to use them. Your surgeon may also give you a protective eye patch to use over the first few days (2 to 5 days) after your surgery. Your surgeon may tell you to limit certain activities for several weeks after the surgery.

You will be asked to return for an eye exam one day after surgery, to make sure that you are recovering as expected.

You should follow all of your surgeon's instructions. They are important. This includes using the eye medications and eye patch as your doctor directs. If you have a sudden worsening of your vision you should contact your doctor as soon as possible.

You should expect improvement in central vision in the intraocular telescope implanted eye to occur over a period of time, from weeks to months.

Do NOT RUB YOUR EYE after the intraocular telescope has been implanted inside your eye. You should not rub your eye for the rest of your life, not just in the immediate postoperative period. Rubbing your eye can damage the corneal endothelial cells. Damaging the corneal endothelial cells can lead to corneal edema and the need for a corneal transplant.

Will You Need Glasses after Implantation of the Intraocular Telescope?

Yes, you will probably need glasses to adjust both your distance and near vision.

Will You Be Able to Drive after Implantation of the Intraocular Telescope?

No. Even with both an intraocular telescope and glasses, you will not be able to drive a car. Your vision will not be good enough (20/40 in most states).

Will you be able to undergo Magnetic Resonance Imaging after implantation?

Yes, the intraocular telescope implant is MR-Conditional as it has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Following surgery you will receive a Patient Implant Card with full details of the MR environment and specified conditions.

Be sure to ask your surgeon any questions you may have regarding magnetic resonance (MR) imaging and the risks of MR imaging after implantation of the intraocular telescope. You may want to refer to the MRI information at: http://www.centrasight.com/implantable_telescope

WHO SHOULD YOU TALK TO ABOUT YOUR QUESTIONS?

You should talk to your eye doctor, the surgeon to whom your eye doctor has referred you, the eye care professionals in their offices and your family and friends.

This Patient Information Booklet provides you with information by asking and answering many questions about the intraocular telescope. In addition, here are a few questions you may want to ask your eye doctor, surgeon or other professionals:

- What are the benefits of the intraocular telescope for my end-stage AMD?
- What are the risks of the intraocular telescope?
- Are there other options for treating my end-stage AMD?
- What is the possibility that the intraocular telescope will not improve my central vision?
- What vision problems may happen with the intraocular telescope implanted in one eye?
- Do I have any conditions that would increase my risk of problems from intraocular telescope surgery?
- Will I be able to drive after getting the intraocular telescope?
- If I am not satisfied with the results after intraocular telescope surgery, will it be necessary for me to have another surgery to remove the intraocular telescope?
- Based on my age and the condition of my cornea, what is my risk of needing a corneal transplant in the future if I have intraocular telescope surgery?
- What could happen if I rub my eye after intraocular telescope surgery?
- Is the intraocular telescope fragile? Can it break in my eye? What would happen if the intraocular telescope breaks?
- How much will the surgery and follow-up cost? Will my health insurance cover this surgery?

ACCEPTANCE OF RISK AND INFORMED DECISION AGREEMENT INFORMATION

You will be given an Acceptance of Risk and Informed Decision Agreement for review and discussion with your eye surgeon. If you accept each risk and sign the Agreement, it means you have decided to have intraocular telescope surgery. You must complete the form by accepting each risk and sign the Agreement before you can have intraocular telescope surgery.

PATIENT ASSISTANCE INFORMATION

Your eye doctor will fill this in so you will know whom to contact if you have any questions about or problems with the intraocular telescope.

EYE DOCTOR

Name: _____

Address: _____

Telephone No: _____

E-mail: _____

SURGEON IMPLANTING THE INTRAOCULAR TELESCOPE

Name: _____

Address: _____

Telephone No: _____

E-Mail: _____

SURGERY LOCATION:

Name: _____

Address: _____

Telephone No: _____

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RM00586-02 REV 3

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ACCEPTANCE OF RISK AND INFORMED DECISION AGREEMENT

To the patient: This is the last step in deciding whether you want to have intraocular telescope surgery. This Agreement lists important risks of intraocular telescope surgery. Please review this Agreement carefully with your eye surgeon. You should sign this Agreement only if you are satisfied that each risk has been explained to you and you understand and accept each risk. If you accept each risk and sign the Agreement, it means you have decided to have intraocular telescope surgery. You must accept each risk and sign the Agreement before you can have intraocular telescope surgery.

To the eye surgeon: Please review this Agreement carefully with your patient. For each item, initial if you are satisfied that the patient understands the item and has accepted it. Your signature confirms that the patient has completed and signed the Agreement.

Patient Initials	Physician Initials
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I understand that the intraocular telescope is implanted in only one eye. The eye with the intraocular telescope provides central vision. I will need to use my other eye for peripheral vision when I want to walk around.

I used an external telescope to see if my vision would improve with magnification and it did. I find the vision acceptable.

**ACCEPTANCE OF RISK AND INFORMED
DECISION AGREEMENT (continued)**

Patient Physician
Initials Initials

I had training in the use of an external telescope to see whether I can adjust to using one eye for central vision and the other eye for peripheral vision. I was able to do this with practice.

I understand that my ability to use the external telescope does not guarantee that I will be able to successfully use the intraocular telescope.

The field of view in the eye implanted with the intraocular telescope is restricted. I understand that I will lose peripheral vision in the eye implanted with the intraocular telescope and that I will need to rely on my other eye for peripheral vision.

I understand that I may experience double vision after intraocular telescope surgery.

I understand that if I have intraocular telescope surgery, I will need training to learn to use the intraocular telescope. I agree to attend such training.

I understand that after intraocular telescope surgery, I will probably need glasses to adjust my near and distance vision.

**ACCEPTANCE OF RISK AND INFORMED
DECISION AGREEMENT (continued)**

Patient Physician
Initials Initials

I understand there may be problems during surgery that may prevent my surgeon from implanting the intraocular telescope. If this happens, I understand that I may receive an intraocular lens (IOL) instead of the intraocular telescope. This means that I will have all the surgical risks, but I will not get the benefits of the intraocular telescope.

I understand that instead of the intraocular telescope improving my vision, my vision could get worse.

I understand that with the intraocular telescope implanted in my eye, my eye doctor may not be able to see parts of my eye or perform some procedures I may need in the future.

I understand that having the intraocular telescope could cause corneal edema. This could happen at any time, even 5 or more years after my surgery, and require me to have corneal transplant surgery.

**ACCEPTANCE OF RISK AND INFORMED DECISION
AGREEMENT (continued)**

Patient Initials	Physician Initials
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If I have to have a corneal transplant, I understand that I may not be able to keep the intraocular telescope in my eye.

_____	_____
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My eye surgeon gave me the Patient Information Booklet on the intraocular telescope. I have had the chance to discuss the information in the Patient Information Booklet with my eye doctor, my eye surgeon, my family and my friends.

_____	_____
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**ACCEPTANCE OF RISK AND INFORMED DECISION
AGREEMENT (continued)**

I have had enough time to read and understand the information in the Patient Information Booklet. My eye doctor and eye surgeon have answered my questions. I have considered alternatives to the intraocular telescope such as external telescopes, spectacle mounted telescopes, and special magnifying eyeglasses.

I choose to proceed with surgery to implant the intraocular telescope.

Patient Name (Printed): _____

Patient Signature: _____

Date: _____

Surgeon Name (Printed): _____

Surgeon Signature: _____

Date: _____

Witness Name (Printed): _____

Witness Signature: _____

Date: _____