CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

SPONSOR COMPANY: Beaver-Visitec International, Inc
500 Totten Pond Road
10 CityPoint
Waltham, MA 02451

PROTOCOL NUMBER PHY2302

PROTOCOL TITLE Clinical investigation of the safety and effectiveness of Monofocal PODEYE TORIC Intraocular Lens (IOL)

STUDY DOCTOR: « Investigator Name»

STUDY SITE ADDRESS: «Study_Site_ Name»
«Site Address_»
«City_State_Zip»

TELEPHONE NUMBER(S): « Site Phone Number»

AFTER HOURS: « 24_Hour_Phone Number»

A. INTRODUCTION

You are being asked to take part in a research study. The following information describes the study and your role as a participant. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the risks and possible benefits of the study are described in this form so that you can make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form explains how your medical information will be used and who may see it. This form also explains your right to stop study participation at any time, which will not affect your current treatment or relationship with the study doctors. Before you decide to volunteer, it is important for you to read all the information in this form. You may have a copy of this form to review at your leisure or to ask advice from others.

Please take your time and read this form carefully. Ask the study doctor or the study staff to explain any words or procedures you do not clearly understand and to answer any questions you may have about this study. If you decide to take part in this study, you will be asked to sign and date the consent form. You may wish to take the consent form home and discuss study

participation with your friends and family before signing it. You will receive a copy of the signed and dated consent form to take home.

The Sponsor of this study is Beaver-Visitec International, Inc. The Sponsor is paying the study doctor and study staff for their work on this research study.

B. STUDY PURPOSE

You are being asked to take part in this study because you have cataracts and corneal astigmatism and are considering intraocular surgery to remove your cataracts. This study is looking at an investigational intraocular lens ("IOL") called the PODEYE TORIC Monofocal IOL. The purpose of the study is to evaluate the safety and effectiveness of the PODEYE TORIC Monofocal IOL and how well it works compared to an FDA-approved Monofocal, Non-Toric intraocular lens (IOL).

There are different types of IOLs available for people who have their cataract removed. Monofocal IOLs allow the eye to focus on a single distance after cataract surgery, often at far distance. Sometimes, for people who have monofocal IOLs, glasses may be needed for best vision when the front part of the eye is curved differently in one direction than the other (astigmatism). Some monofocal IOLs allow for this correction of astigmatism. These IOLs are called toric IOLs. Use of glasses is still needed to focus at several distances, often at middle and/or at near (for example, computer work and reading), with both monofocal IOLs (non-toric) and monofocal toric IOLs lenses.

The PODEYE TORIC Monofocal IOL is a permanent artificial lens that replaces the cloudy natural lens [cataract] that is removed during cataract surgery to restore vision. The PODEYE TORIC Monofocal is made of a hydrophobic (water/eye fluid repellant) material that can be folded for insertion through the same small incision used to remove the cataract.

This product is considered to be "investigational" because this IOL has not yet been approved for sale or use in the United States (U.S.) by the U.S. Food and Drug Administration (FDA).

The IOL being used for comparison to the PODEYE TORIC Monofocal IOL is called the AcrySof SA60AT. This IOL is manufactured by Alcon and is approved for use in the United States by the FDA. This lens is a monofocal, non-toric IOL and can only correct your vision at one distance, this lens does not correct for astigmatism. This IOL is a non-toric lens and does not correct for astigmatism, therefore glasses will be needed to correct for astigmatism if you receive the AcrySof SA60AT monofocal, non-toric IOL.

C. RESEARCH STUDY DESIGN

Up to 300 male and female adults who are 22 years or older with cataract and pre-existing corneal astigmatism who need to have cataract surgery are expected to take part in this study. Study participants are expected to be enrolled at up to 10 study centers located in the U.S.

If you agree to take part in this study, your involvement will last approximately **9 months**. You will be asked to come to the clinic a total of at least 6 times. Each clinic visit will take between 1-2 hours depending on the type of visit, apart from the cataract surgery visit, which will take between 2-4 hours. There may also be additional visits at any time if you wish to be seen for any reason.

All participants must attend a preoperative screening visit, which must occur no more than 90 days prior to surgery to determine if they qualify to take part in the study. Those who qualify at the preoperative visit will undergo cataract removal surgery and planned implantation of either the test lens: PODEYE TORIC Monofocal IOL, or the control lens: AcrySof SA60AT monofocal, non-toric IOL.

Each participant will be randomized 1:1 (50% chance) to which IOL they receive. Participants are just as likely to receive the PODEYE TORIC Monofocal IOL as they are to receive the AcrySof SA60AT monofocal, non-toric IOL.

If you receive the AcrySof SA60AT monofocal, non-toric IOL, it will not correct for astigmatism and therefore glasses will be needed to correct for astigmatism if you receive this lens.

After your cataract surgery, you must return for follow-up visits. You will need to complete 4 follow-up visits after surgery over the course of 6 months.

At each scheduled visit, the study doctor and study staff will evaluate participants' vision and any health complications or complaints that may be related to the study device (implanted IOL).
This study is a double masked study, which means that neither you nor the assessors (study personnel performing the study assessments) will know which IOL you received. The study doctor can obtain this information if this information is needed for your safety.

D. STUDY PROCEDURES

Before you begin participation, the study must be explained to you and all of your questions must be answered to your satisfaction. You must read and sign this informed consent form. Afterwards, a copy of the signed informed consent form will be given to you. If you do take part in the study, your experience will be very similar to that of patients undergoing routine cataract surgery, but some of the follow up examinations will take more time due to more extensive testing.

At the end of the study visits, you will be exited from the study and will be scheduled for routine follow up visits according to standard of care. The activities that will occur at each scheduled visit in the study are summarized below.

Study Visits

1. Preoperative Visit (to determine your eligibility for the study)

The preoperative visit will take about 2 hours to complete. The following exams and procedures will be performed:

- You will come to the clinic for a screening visit to determine if you are eligible and willing to participate in this study. Prior to any procedures being performed, you will be asked to read, sign and date this Consent to Participate in a Clinical Research Study and Authorization to Health Information.
- You will be asked to provide information about yourself, including your date of birth gender and personal data (information)
- You will be asked about your current overall health and the condition of both of your eyes. You will also be asked about any previous medical conditions or treatments you have had. You must be honest in providing information about your eyes and your overall health. Giving false or incomplete information could have serious health consequences. You will be asked to take a urine pregnancy test, if applicable.
- A list of the medications you are taking now and have taken in the past will be recorded.
- If both eyes are candidates for the study, then the vision in each of your eyes will be checked to determine how well you see. Vision will be checked in each eye separately. Vision will be checked with correction (glasses or contact lenses) and without correction. If only one eye is a candidate, then Vision will only be checked in that eye.
- If both eyes are candidates for the study, the refractive error in both eyes will be measured, using a process called “manifest refraction”. This is the same process that is done in order to get prescription glasses or contacts. If only one eye is a candidate, then manifest refraction will be done in that eye.
- The size of your pupils will be measured after dilation.
- Numbing drops will be put in your eye(s) and your eye pressure will be measured by touching an instrument to your cornea, which is the clear front window of your eye. The study doctor might also use an orange/yellow (fluorescein) dye as well. Because your eyes are numb, you should feel no pain during this procedure.
- The front part of both of your eyes will be examined using a bright light and a special microscope called a slit lamp.
- Dilating drops will be put in each of your eyes to enlarge your pupil (the black circle in the center of the colored part [the iris] of the eye). The study doctor will use a magnifying lens and a bright light to examine your retina, which is the back of your eye. The effect of these

drops will last approximately 4 - 5 hours and, during that time, you should not drive a car or operate machinery.

- The anatomy of your eyes will be measured using a non-contact instrument to determine the necessary IOL power (prescription) to provide you with good vision, and to measure the length and depth of structures within your eye(s).
- The shape and curvature of your corneas (clear part of the front of your eyes) will be measured using a non-contact instrument.

Based on the information gathered during this exam, the study doctor will determine if you meet the criteria for further study participation. If you are qualified to continue in the study, you will be scheduled for cataract surgery, including implantation of one of two IOLs. The IOL implanted will be chosen at random to be the PODEYE TORIC Monofocal IOL or the AcrySof SA60AT monofocal, non-toric IOL. In the days just before surgery, the study doctor may ask you to begin using eye drops to minimize swelling and infection that may result from the surgery.

2. Cataract Surgery (to remove your cataract and place the IOL in one eye selected for the study)

Your cataract surgery will be performed in an operating room at a clinic or hospital. You should plan that you will be there for 2 – 4 hours. Please make certain someone is available to take you home after surgery.

You will have your cataract removed and if there are no complications, either the PODEYE TORIC Monofocal IOL or the AcrySof SA60AT monofocal non-toric IOL will be placed in your eye in the location where the natural lens was located. If there are complications during your surgery prior to the lens being placed, then your study doctor will replace your natural lens with a non-study IOL that is approved by the FDA. Your eye will be examined to assess the IOL position. After surgery, your study doctor will ask you to continue use of eye drops for about 4 weeks to prevent swelling and infection. The study doctor or study staff will provide instructions on how to use these drops.

3. Post-Surgery Visits (to evaluate your vision and the health of your eyes)

You will be scheduled to return for 4 follow-up clinic visits during the approximately 6 months after your cataract surgeries, to evaluate the eye implanted for the study. These visits may require 1 – 2 hours of your time. The visits must follow the schedule below:

- Visit 1: 1-2 days after surgery
- Visit 2: 7-14 days after surgery
- Visit 3: 30-60 days after surgery
- Visit 4: 120-180 days after surgery

The following study exams and procedures may be performed at these visits:

- You will be asked how you are feeling and if you have had any changes in your health or medications used since your last visit.
- A list of the medications you are taking now and have taken since your last visit will be recorded.
- A slit lamp exam, using a magnifying instrument, will be performed to evaluate the condition of the front part of your eye. During this exam, the IOL will also be evaluated. Pictures of your eye may be taken during the slit lamp exam.
- Numbing drops will be put into your eyes, and your eye pressure will be measured.
- Dilating drops will be put in your eyes to enlarge your pupils to examine the lens and your retina. The effect of these eye drops will last approximately 4 – 5 hours and, during that time, you should not drive a car or operate machinery.
- The shape and curvature of your corneas (clear part of the front of your eyes) will be measured using a non-contact instrument.
- Your vision will be checked with correction (glasses) and without correction to determine how well you see at distance.
- Your refractive error or the prescription will be measured, using a process called "manifest refraction". This is the same process that is done when getting a prescription for glasses or contacts.
- The study doctor will record any IOL faults or possible problems with the study IOLs or with your eyes that are observed during the eye exams.

4. Unscheduled Visits

If you have any problems with your vision between scheduled follow-up visits, you should contact your study doctor who may request that you return for an unscheduled visit.

You may also be asked to return for 1 or more unscheduled visits if there are changes in the health of your eyes during the study, or if you decide to discontinue study participation for any reason. If you are asked to return for an unscheduled visit, some or all of the exams listed above may be performed. Your study doctor will decide which exams are appropriate during the unscheduled visit.

E. SAFETY ASSESSMENTS

At times specified in this consent form, you will be asked to read an eye chart and have your eyes examined by the study doctor to test for any sight threatening adverse events (unfavorable side effects) associated with any of the devices being used in this study.

F. RESPONSIBILITIES OF THE PARTICIPANT

Taking part in a research study can be an inconvenience to your daily life. Please carefully consider the time commitments and responsibilities you will be undertaking. Your responsibilities as a study participant are to:

- Tell the truth about your medical history, current conditions and any prescription or over-the-counter medications you are taking.
- Tell the study doctor if you have been in a research study during the past 30 days or are in another research study now. You will not be able to enroll in any other clinical study of an investigational drug or device until you have completed participation in this study.
- Go to all your scheduled study visits.
- Follow all instructions given by the study doctor and study staff.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- If you typically wear rigid gas permeable (RGP) or toric contact lenses, you must not put them in the eye to be implanted in the study for at least 7 days before your pre-operative visit.
- If you typically wear non-toric soft contact lenses (SCL), you must not put them in the eye to be implanted in the study for at least 3 days before your pre-operative visit.
- If you are female and able to become pregnant, you will be asked to use medically acceptable birth control and to prevent pregnancy. Acceptable methods include at least one of the following: intrauterine (intrauterine device [IUD]), hormonal (oral, injection, patch, implant, ring), barrier with spermicide (condom, diaphragm), or abstinence.

POSSIBLE RISKS AND DISCOMFORTS OF YOUR PARTICIPATION IN THE STUDY

If you decide to participate in this study, you will have cataract surgery. The risks and benefits for this procedure should have already been reviewed with you. There may be harmful effects that can occur from receiving the study device. Some effects may be mild and might not last long while some of the potential risks may be serious and/or long-lasting. Treatment with any device presents potential risks. There may also be risks associated with the preoperative and postoperative medications you may be asked to use before and after surgery.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

Anticipated adverse effects associated with cataract surgery and/or IOL implantation include, but are not limited to, the following:

- Increased pressure in your eye
- Swelling of the clear outer layer at the front of the eye (corneal edema)
- Blurred vision

- Decrease in how well you distinguish shapes and details at a given distance

You may experience complications that are more difficult to manage and may cause serious problems, such as:

- Swelling of the eye (eye edema)
- Eye infection (endophthalmitis [inflammation of intraocular fluids], keratitis [inflammation of the cornea])
- Damage to the colored (iris) or black part (pupil) of your eye
- Inflammation inside your eye that is temporary or that lasts for more than 3 months after surgery (anterior uveitis including iritis)
- Eye pain that lasts for a long time (chronic)
- Retinal detachment (when the light-sensitive layer of tissue is pulled away from its normal position at the back of your eye)
- Visual symptoms that can include glare, starbursts, rings, halos, or flashes of light
- Fluid filled pockets in the back of the eye (macula) causing the lining in the back of your eye (retina) to swell (Cystoid macular edema)
- Buildup of white blood cells in the front of the eye (hypopyon)
- A blockage of the natural flow of the liquid (aqueous humor) inside the eye (Pupillary block)
- Cloudy layer of scar tissue behind the lens implant (Posterior capsule opacification)
- Collection of blood inside the front of the eye (Hyphema)
- Issue where the pocket made for the IOL contracts too much, potentially requiring additional intervention (Anterior capsule phimosis)
- Leaking of fluid from the surgical incision site
- Loss of vitreous (gel-like fluid that fills your eye)
- Breaking of the barrier between the front and back part of eye (Posterior capsule rupture)
- IOL dislocation, tilt, decentration, luxation (shifting), rotation (unwanted movement of the lens inserted during surgery)
- Secondary surgical intervention (including but not limited to lens repositioning, lens replacement, wound leak repair, retinal detachment repair)
- Loss of visual acuity/vision

There are some additional risks associated with implantation of toric lenses.

- In some cases, patients receiving toric intraocular lens correction also have an increased risk of needing another surgery to correctly position the IOL to provide clear vision.

Some of these problems may create the need for further surgery or to remove the study device.

Since it is impossible to state every complication that may occur as a result of the surgery, the list of complications in this consent form is not complete. There may be rare or unknown side effects that could possibly occur, including life-threatening reactions. You should discuss these risks with your family doctor to see if he or she feels that you are a good candidate for this kind of surgery. Fortunately, the most serious complications (such as infections, retinal detachment) are uncommon (less than 1% of cases).

In the exam where your eye pressure is measured, there is a risk that your cornea may receive a minor scratch from the instrument that touches the cornea. Minor scratches of this nature usually heal within 24 hours.

In the exam where eye drops are used to make your pupil large, there are risks of temporary glare and blurring of your vision. The eye drops could make your eye pressure higher. You may have an allergic reaction to these eye drops. This reaction could be very minor such as some eye redness. However, it could also be a more serious reaction such as a severe allergic reaction called anaphylaxis. Other uncommon effects may include dizziness, increased sweating, increased blood pressure, abnormal heart rhythm, or slow heart rate. Your Study Doctor will discuss these risks with you. You should avoid driving until your vision returns to normal. To protect your eyes until your pupil returns to normal size, you should wear sunglasses while outside. The study doctor will monitor your eye pressure closely and may take steps as necessary to reduce the pressure if it increases too much.

The orange-yellow (fluorescein) dye that will be put in your eye to evaluate the intraocular pressure (pressure inside your eye) may make your skin and bodily secretions and excretions, such as your tears or mucous, change color, or they may cause some irritation to your eye. This effect is usually temporary and disappears within a day. Rarely, people can have an allergic reaction to fluorescein dye. This would usually involve itching, swelling, or redness. If you develop this reaction, you will receive treatment.

Women who are pregnant, planning to become pregnant or nursing a child may not take part in this study. Risks to women who are pregnant or nursing are unknown. The study IOLs might involve risks to the unborn baby, which are currently unforeseeable. If you suspect that you have become pregnant, you must notify the study doctor immediately.

G. NEW FINDINGS

New information may develop from this study that may be important for your health or might change your decision to be in the study. You will be informed if such information becomes available. You may be asked to sign a revised consent form if changes occur in the study. Even if the study has ended, if this type of information becomes available, it will be given to you.

H. YOUR BENEFITS OF PARTICIPATION

It is not anticipated that your receipt of the investigational IOL or FDA approved IOL will provide any additional benefits beyond those that other currently approved IOLs would offer. Like all IOLs, the investigational IOL may provide you with a better visual outcome than other treatments after cataract surgery (spectacles or contact lenses) because IOLs provide a more normal image size on the retina. This study may help surgeons in the future to select the most suitable implant for patients undergoing cataract surgery.

I. YOUR ALTERNATIVES TO PARTICIPATION

You may decide not to have cataract surgery. However, if you decide to have this operation, you should understand that there are 3 regularly used methods of restoring useful vision after the natural lens of the eye (cataract) is removed at the time of surgery:

- **Glasses:** Cataract glasses are usually thicker and heavier than conventional eyeglasses. They increase the size of objects by about 25%, and clear vision is obtained only through the central part of cataract glasses, which means you must turn your head to see clearly to either side. Cataract glasses cannot be used if a cataract is present only in one eye, because they may cause double vision. Cataract glasses are used when an IOL has not been implanted in the eye during cataract surgery.

- **Contact Lens:** A hard or soft contact lens makes objects look about 8% larger than actual. Handling of a contact lens is difficult for some individuals. Most contact lenses must be inserted and removed daily and not everyone can tolerate them. For tasks where near vision is important, eyeglasses are often required in addition to contact lenses. These types of contact lenses are used when an IOL has not been implanted in the eye during cataract surgery.

- **FDA-approved Intraocular Lens:** An IOL is a small permanently implanted artificial lens made of rigid plastic, silicone, acrylic, or other suitable material (some with supports made of plastic materials such as polyimide, polypropylene, PMMA, or other suitable material). With an IOL, there is no apparent change in the size of objects seen. While your vision following cataract surgery with an IOL may be quite good, the use of conventional eyeglasses may also be required to give the best vision possible. There are many soft foldable and rigid IOLs that are approved for use by the FDA. Specialty lenses usually have additional costs. There are FDA approved multifocal IOLs available that correct vision to allow you to see both near and distance objects that reduce the need for glasses. There are FDA-approved monofocal, toric IOLs available that correct for astigmatism that reduce the need for glasses.

The study doctor will discuss with you the important potential benefits and risks of the alternative treatments.

J. COST OF TREATMENT

The study visits, study device and study-related procedures, including your cataract surgery, will be provided at no cost to you or your insurance company. Ask the study doctor or study staff to discuss any additional costs of study participation, such as expenses associated with attending required study visits, and how they will be covered. You and/or your insurance company will be billed for any standard care unrelated to the study that you receive during your study participation.

K. PAYMENT FOR PARTICIPATION

You will receive up to a total of $300.00 for completing the study. You will be paid the following amount for each study visit to compensate for your time and the inconvenience related to study participation:

Visit	**Payment**
Visit 0 (Preoperative Visit)	$50.00
Visit 00 (Surgery Visit)	$50.00
Visit 1 (1-2 Day Visit)	$50.00
Visit 2 (7-14 Day Visit)	$50.00
Visit 3 (30-60 Day Visit)	$50.00
Visit 4 (120-180 Day Visit)	$50.00

Optional language per site specific budget<<If the study doctor asks you to return for an unscheduled visit, you will be paid $XX for each unscheduled visit you complete.>>

If you leave the study before completing all visits, you will be paid for each completed visit. You will receive payment <<insert site specific payment schedule>>. Because payments made to you for taking part in this study may be reported to the IRS as income, you may need to provide your Social Security Number.

L. YOUR RIGHTS

Your participation in this study is completely voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled and will not interfere with your future care at this facility or by doctors at this facility. You do not waive any of your legal rights by signing this form.

Your study doctor/or the Sponsor may stop your participation in the study without your permission at any time if it is deemed that continuation in the study will put your safety at risk. If you are prematurely discontinued from the study, your study doctor will still continue to monitor you for safety. The following people/organizations can stop your participation and/or the study itself: your study doctor, the Sponsor, Alpha IRB, or the United States Food and Drug Administration (FDA).

If you wish to leave this study before completing all study visits, please inform the study doctor or study staff. You may use the telephone number listed on the first page of this form to let them know of your decision. If you do not want to be in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you withdraw from the study, no new data about you will be collected for study purposes. All data that have already been collected for study purposes will be shared with the study Sponsor.

Your primary care physician (PCP) should know that you are taking part in this study. You should take steps to inform your PCP prior to starting study participation.

M. WHAT IF THE SPONSOR OR STUDY DOCTOR DECIDES TO STOP THE STUDY?

The Sponsor or study doctor can decide to stop the study at any time. Your participation in this study may be stopped if you do not follow the study doctor or staff's instructions or if your study doctor feels that it is necessary for your health or safety. You may be asked to leave the study even if you do not want to leave. If you decide to leave the study or are taken out of the study, you may be asked to return for additional visits to make sure that you are in good health.

If you leave the study, data (information) collected on you to the point of withdrawal remains part of the study database and may not be removed.

The study doctor, the Sponsor or its representatives, or Alpha Independent Review Board may take you out of the study without your permission, at any time, for the following reasons:

- If they find out you should not be in the study
- If the study is stopped

If it becomes harmful to your health (please note that if you experience any side effects, your study doctor will make sure medical treatment is available to you at least until the side effect is stable or has recovered).

N. COMPENSATION FOR INJURY

After you have received the study device, if you have any side effects or injuries, you must tell the study doctor as soon as possible. Your study doctor will make sure medical treatment is available to you.

If side effects or other injuries are the direct result of the study device or procedures, immediate medical care will be provided to you upon your consent. The Sponsor will cover any reasonable costs to treat such side effects or injuries. If a side effect or injury is due to any of the following reasons, the Sponsor does not offer to cover your treatment costs:

- You did not follow the instructions given to you by your study doctor
- You caused your own side effect or injury
- The study doctor or study staff did not follow the study plan
- The side effect or injury is a normal progression of an underlying medical condition that was present when you enrolled in the study.

The Sponsor has no plans to provide compensation for any expenses other than the cost of immediate medical treatment of a side effect or injury that is the direct result of the study device or study procedures. If your side effect or injury is not a direct result of study participation, you or your medical insurance will be billed for the cost of treatment. This does not prevent you from pursuing other legal options. You do not give up any legal rights by signing this form.

To help avoid study-related side effects or injuries, it is very important to follow all study directions given to you by your study doctor.

If you become ill or get hurt during the study, please contact the Principal Investigator at the telephone number listed on page 1 of this consent form.

O. WHO CAN SEE OR USE MY PERSONAL INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Information obtained about you for this study will be kept private to the extent allowed by law. Your personal health information may be shared with certain people from certain organizations, known as "authorized users," who need to see, copy, and/or use this information in order to do their part in the study. The authorized users will receive full access to your original personal health information, which may or may not include your name. It is possible that your personal health information can be traced back to you even if it does not include your name. Therefore, complete privacy of your health information may not be possible. By signing this consent form, you are giving your study doctor permission to share your personal health information with all authorized users.

Authorized users may include, but are not limited to:

- **Representatives of Beaver-Visitec International, Inc, companies who work with Beaver-Visitec International, Inc, its affiliates, agents, contractors and third parties.**
- **Representatives of True North Contract Research, Inc.**
- **Representatives of the Study Site**
- **The Food and Drug Administration (FDA) and other US governmental agencies, or similar regulatory agencies in other countries**
- **Alpha IRB**

Information obtained from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. Because this study involves an investigational product, the description may not appear until after the study is complete.

For safety reasons, your primary health care provider should know that you are taking part in this study. However, your study doctor will need permission from you before he or she can notify your primary health care provider. You will be asked to complete the Primary Care Physician/Specialist Notification option form below that will allow your study doctor to notify your primary health care provider.

P. SOURCE OF FUNDING

Beaver-Visitec International, Inc is organizing this study to be conducted at the Study Site by the Principal Investigator. The study doctor (i.e. principal investigator) and/or institution are being paid by Beaver-Visitec for the work done for this study. Beaver-Visitec International, Inc is supplying the intraocular lenses as well as all surgical fees and follow-up visits at no cost to the participants.

Q. WHO CAN I CALL IF I HAVE QUESTIONS ABOUT THE STUDY AND MY RIGHTS AS A RESEARCH PARTICIPANT?

If you have any questions, concerns or complaints about this study or to report a study related injury, contact the study doctor at the telephone numbers listed on page 1 of this consent form.

If you have questions, concerns or complaints about your rights as a research volunteer or about taking part in this study, or to obtain information or offer input, you may contact Alpha IRB, toll free at (888) 265-5766 between the hours of 8:00am-5:00pm Pacific Time.

Alpha Independent Review Board
1001 Avenida Pico, Suite C #497
San Clemente, CA 92673
(888) 265-5766 (toll free)

Alpha IRB is a group of people who perform independent review of research studies to protect the rights and welfare of study participants. Although Alpha IRB has approved the information provided in this informed consent form and has approved for the study doctor to do the study, this does not mean the Alpha IRB has approved you being in the study, or that the study is without risks. You must consider the information in this consent form for yourself and decide if you want to be in this study.

Thank you for taking the time to read this information. Please feel free to ask any questions.

If you would like to participate in this study, you will be requested to sign the attached consent form, in order to proceed. Do not sign this consent unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. You will be given a copy of the document.

R. CONFIDENTIALITY

Records of you being in this study will be kept confidential except as required by law. Your personal health information may be shared with certain people from certain organizations, known as 'authorized users' who need to see, copy and/or use this information in order to do their part in the study. The authorized users will receive full access to your original personal health information, including direct access to your original medical records, for verification of clinical trial procedures and/or data (information). However, this will be done without violating your confidentiality to the extent permitted by the applicable laws and regulations.

The following people will have access to your study records:

- The study sponsor and monitors and representatives
- Applicable personnel in the Food and Drug Administration (FDA)

- Department of Health and Human Services (DHHS) agencies or other regulatory authorities as required by law
- Alpha Independent Review Board (Alpha IRB)

If the study results are presented at meetings or printed in publications, your name or other information that identifies you will not be used.

You should be aware that your personal identifiers might be removed from the identifiable private information, making it unlikely that anyone will be able to identify you. After such removal, the information might be combined with data from other studies or could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. This is intended to better understand the safety and effectiveness of the investigational IOL. You will not know the results of any future study-related research performed using your information and such information will not be placed in your medical records. Results of the study may be reported to any national regulatory agency and may also be used in scientific publications and/or presentations, but no personal details will be released. By signing this Informed Consent document, you are authorizing access to your records.

If commercial products or other valuable discoveries result from research using your data (information), these products and discoveries may be owned, patented, licensed, or otherwise developed for commercial sale by the sponsor, other researchers, or companies. If this should occur, you will not receive any payment or have any ownership or rights from any discoveries that may result from such research.

PRIMARY CARE DOCTOR / SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____ Yes, I want the study doctor to inform my primary care doctor/specialist of my participation in this study.

_____ No, I do not want the study doctor to inform my primary care doctor/specialist of my participation in this study.

_____ I do not have a primary care doctor/specialist.

_____ The study doctor is my primary care doctor/specialist.

STATEMENT OF CONSENT

I have read this form and its contents were discussed with me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I am aware that by signing this consent form I am authorizing (giving permission for) the use and possible disclosure (sharing) of my personal health information (PHI). I will receive a copy of this signed and dated consent form for my records. I am not giving up any of my legal rights by signing this form.

_____
Printed Name of Subject

_____ ____/____/_____
Signature of Subject Date DD / MMM/ YYYY

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully discussed with the subject the nature and purpose of the above study. The subject has had time to review this form and had an opportunity to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____
Printed Name of Person Discussing Consent

_____ ____/____/_____
Signature of Person Discussing Consent Date DD / MMM/ YYYY