APPROVED
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WIRB®

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A PROSPECTIVE MULTI-CENTER STUDY OF ANTERIOR LENS CAPSULOTOMY USING THE MYNOSYS ZEPTO™ SYSTEM

PROTOCOL NO.: MYN-002
WIRB® Protocol #20161944

SPONSOR: Mynosys Cellular Devices, Inc.

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SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will perform the cataract surgery using standard techniques.
- Parts of this study involve experimental (investigational) capsulotomy procedures that are being tested for a new device. An investigational device is one that has not been approved by the U.S. Food & Drug Administration (FDA).

- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.

- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

- Your medical insurance WILL be billed for any standard medical care you receive during the research study. You will be responsible for the costs of your standard medical care. You will not be charged for the study portion of your care. Your insurance company will not be billed for the research portion of your care. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

PURPOSE OF THE STUDY

The purpose of this study is to determine whether the Mynosys Zepto™ System is safe and effective in performing anterior capsulotomies during cataract surgery.

PROCEDURES

You will have eye surgery to have cataracts removed and as part of the surgery, a capsulotomy will be performed using the Mynosys Zepto™ System. The only investigational aspect of this study is use of the Zepto device to perform the capsulotomy procedure, all other surgical procedures and postoperative follow-up evaluations are standard of care.

The Zepto™ device consists of a small disposable surgical handpiece connected to an electronic console. The Zepto™ handpiece tip has a small suction cup containing a small metal ring.

A Zepto™ capsulotomy is a surgical procedure in which the tip of the Zepto handpiece is inserted into the eye and centered over the anterior lens capsule. Suction is applied to the suction cup containing the metal ring and 12 very short electrical pulses will be delivered in less than 1 second resulting in a circular incision in the capsule of the crystalline lens of the eye. This procedure will take less than 1 minute. After that, the device will be removed from your eye. After completion of the capsulotomy, the physician performs the rest of the cataract surgery procedure following his standard routine for this surgery.

As part of the study you will be required to return to your Physician for 3 additional routine office visits 1 day after, 1 week after and 1 month after the procedure.

After the surgery, you will be prescribed with antibiotic eye drops to prevent infection and anti-inflammatory eye drops to help reduce any internal inflammation. You'll need to apply the eye drops several times daily for about the first week during your recovery from cataract surgery. This medication is not part of the study, but is standard treatment for cataract surgery.

All qualified subjects in the study will have a capsulotomy created by the Mynosys Zepto™ system. If both your eyes require cataract surgery, only one eye will have a capsulotomy with the

Zepto™ system. The other eye will receive a capsulotomy using your physician's standard technique. The eye receiving the Zepto™ capsulotomy will be chosen randomly.

RISKS AND DISCOMFORTS

- **What are the possible risks or discomforts?**
- ***Risks of Eye Examination and Dilation:***

As part of the eye exam, drops will be put in your eyes to dilate the pupils. This is a standard procedure during cataract surgery and not specific to the study. The drops may blur your vision and make you sensitive to light for several hours. There is a small risk of an allergic reaction to the drops. There is also a small risk that the drops could cause the eye pressure to raise. If this happens, it will be treated, but there is a very small risk of losing vision from the pressure rise. Due to the blurring effect of your vision and possible light sensitivity, you will be advised not to drive until the drops have worn off and, if necessary, to have someone come with you who can drive after the exam.

Subjects enrolled in the study will be required to commit to the following examination schedule and take part in the clinical evaluations:

- Preoperative Evaluation (Day -14 to Day -1)
- Operative Evaluation (Day 0)
- Day 1 (1 to 2 days postoperative)
- Week 1 (5 to 12 days postoperative)
- Month 1 (3 to 6 weeks postoperative)
- Month 3 (11 to 14 weeks postoperative

The following list of clinical parameters is typically collected as part of routine pre-operative testing. If they are not collected as part of the routine pre-operative examination, they will be collected as study specific procedures prior to cataract surgery.

- 1. Manifest refraction
- 2. Uncorrected distance visual acuity (UCVA)
- 3. Best spectacle corrected distance visual acuity (BSCVA)
- 4. Dilated pupil size
- 5. Slit lamp and fundus examination

- ***Other Risks from Cataract Surgery:***

  You should be aware that there may be additional risks or side effects that are currently unknown and unforeseeable.Feel free to ask the study doctor any questions you have about these risks such as the frequency that these side effects may occur in surgeries like yours. For example:

- the risks of anterior capsular tears to the eye (an unintended tear in the front part of the capsule bag that surrounds the lens of the eye, such tears can sometimes extend posteriorly and cause surgical complications such as inability to insert the intended intraocular lens (IOL) implant, loss of some of the clear gel that fills the back of the eyeball which requires additional surgical procedures for removal and potential complications of retinal detachment and permanent vision loss) are not known.

- the risks of posterior capsular tears/rupture to the eye (an unintended tear in the back part of the capsule bag that surrounds the lens of the eye, often associated with inability to implant the intended intraocular lens (IOL) in the capsule bag which is the standard location, loss of vitreous (the clear gel that fills the back of the eyeball) and need for additional surgical procedures for its removal, and potential complications of retinal detachment and permanent vision loss) are not known.

- the risks of loss of visual acuity that is not correctable with glasses is unknown.

- the risks of choroidal effusion hemorrhage, a buildup of fluid between the choroid (the blood vessel layer that nourishes the overlying retina) and the sclera, the white outer covering of the eye is not known. This can be associated with permanent vision loss and other complications.

- the risks of corneal edema (swelling of the cornea) and corneal cloudiness is not known.

- the risks of corneal abrasion, the scraping away of the cornea by external physical forces is not known.

- the risk of corneal decompensation (swelling of the cornea due to a failure of the corneal cells to remain relatively dehydrated).

- the risks of post-operative uveitis, swelling or inflammation of the uvea, the middle layer of pigmented vascular structures of the eye is not known.

- the risks of endophthalmitis, an inflammation of the internal coats of the eye including intraocular infection which can be associated with significant permanent vision loss is not known.

- the risks of posterior capsule opacification (cloudiness of the posterior capsule) is not known.

- the risks of macular edema, a swelling of the central portion of the retina with associated loss of vision is not known.

- the risk of retinal tear or retinal detachment (a separation of the retina from the back of the eye) is not known.

- the risk of posterior vitreous detachment (gel which fills the eye behind the lens separates from the retina) is not known.

- the risks of elevated intraocular pressure, fluid pressure inside the eye is not known.

- the risks of decentered (malpositioning) IOL is not known.

- the risks of wound leak is not known.

- the risks of posterior vitreous detachment, the vitreous membrane separating from the retina is not known.

- The risks of medication allergy and intolerance is not known.

- the risks of ptosis, a drooping of the upper eyelid is not known.

- ***Device Related Risks:***

  You should be aware that there may be additional risks or side effects that are currently unknown and unforeseeable. For example:

- the risk of ocular tissue damage by the device energy is not known.

- the risk of incomplete capsulotomy requiring manual completion with or without capsule tear or other injury requiring alternative IOL and/or anterior vitrectomy. Risks from anterior vitrectomy are bleeding in the eye as well as retinal detachments (a break in the retina that then allows the fluid in the eye to get behind the retina) which requires additional surgical procedures for removal and potential complications of retinal detachment and vision loss). Other possible risks which are not known include:

- the risk of capsulotomy decentration (the circular hole cut in the lens is not centered).

- the risk of zonular instability (the fibrous strands that connect the ciliary body with the capsule bag can become displaced).

- the risk of intraocular lens (IOL) decentration (the intraocular lens in not centered).

- the risk of corneal burn (a burn to the cornea).

- the risk of corneal endothelial tear (a tear in the single layer of cells on the inner surface of the cornea).

- the risk of anterior capsule fibrosis/anterior capsule contraction syndrome (the capsule contracts and becomes thickened and scarred).

  Women who are pregnant may not take part in this study. Women that have not been confirmed to be post-menopausal or surgically sterilized will be given a Serum β-HCG test prior to your cataract surgery to confirm that you are not pregnant.

Other Risks
Your condition may not get better or may get worse during this study. As the surgery you are scheduled is not part of this research you will be asked to sign a separate consent form for it.

BENEFITS

It is possible that the Mynosys Zepto™ System could create a well-placed capsulotomy without exposure to laser energy or some shortcomings of the manual Continuous Curvilinear Capsulorhexis (CCC). However, this is an initial study so there is no clinical evidence to support this at this time. The information from this research may help others in the future.

COSTS

You will be charged for standard medical care. You will not be charged extra for the study portion of your care. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

FINANCIAL DISCLOSURE

Dr. Thompson owns stock and has received consulting and speaking fees from the sponsor in the past 12 months. Please feel free to ask any further questions you might have about this matter.

PAYMENT FOR PARTICIPATION

You will receive limited payment for travel expenses for being in this study. You will be reimbursed $50 for each study visit after the initial screening visit. Reimbursement is to defray travel costs.

ALTERNATIVE TREATMENT

If you choose not to participate in this study, your doctor will discuss alternative surgical techniques to perform the capsulotomy required for your cataract surgery.

You do not have to take part in this study to receive treatment for your condition. One of the surgical alternatives available to people with cataracts requiring a capsulotomy is a technique called a Continuous Curvilinear Capsulorhexis (CCC). CCC is the current standard of care in which the doctor creates a puncture in the central part of the anterior lens capsule and then manually uses forceps to tear a circular hole approximately 5-mm in diameter.

The treatment may also be done using a femtosecond laser. You may also choose to receive no treatment at all.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- Working for or with the sponsor, or
- Owned by the sponsor.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

This permission will not expire or will be good until December 31, 2060.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.
When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Confidentiality
Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the Zepto™ System may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor,
- Promedica, an agent for the sponsor,
- Kevin Waltz, O.D., M.D., the medical monitor for this study,

And may be looked at and/or copied for research or regulatory purposes by:

- the FDA,
- Department of Health and Human Services (DHHS) agencies,
- California State Food and Drug Branch
- governmental agencies in other countries, and
- Western Institutional Review Board® (WIRB®).

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." [21 CFR 50.25(c)].

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of study procedures, call the study doctor immediately. The study doctor will provide emergency medical treatment. Compensation will be provided for any additional medical charges as a result of an injury caused by the Zepto™ device.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is 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.
Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest
- if you do not consent to continue in the study after being told of changes in the research that may affect you

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

QUESTIONS
Contact Dan Marinsik at (510) 857-6296 (24-hours) or Dan Marinsik at 510-857-6296 (24-hours) for any of the following reasons:

- if at any time you feel you have had a research-related injury, or
- if you have questions, concerns, or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the release of my medical and research records for the purpose of this study.
By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

_____ _____
Signature of Subject Date

_____ _____
Printed Name of Person Conducting the Informed Consent Discussion Position

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date

Ver. 08/17/2016