INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Eric J Poulsen, MD / "Hydrus Microstent as a Quality of Life Consideration"**
Principal Investigator: (Study Doctor)	**Eric Poulsen, MD**
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KEY INFORMATION

You are invited to take part in a research study. This research study is assessing the benefits of the U.S. Food and Drug Administration (FDA)-approved Hydrus Microstent to treat mild-to-moderate open angle glaucoma at the time of cataract surgery. The primary benefits are thought to be decreasing intraocular pressure and reducing the need for glaucoma eyedrops. Reducing the need for glaucoma eyedrops may improve quality of life.

Alcon, the manufacturer of the Hydrus Microstent, is providing a research grant to conduct this research study.

- ***Main reason to join this study:*** *Be part of research to determine the benefits of this FDA-approved microstent for glaucoma and receive quality evaluation and care of your glaucoma.*
- ***Main reason not to join this study:*** *If you are unable to have follow ups with your eye surgeon and/or the study doctor for the four months after surgery.*
- ***Research question the study is trying to answer:*** *Does the Hydrus microstent improve quality of life for glaucoma patients?*
- ***What information about you is being collected for the study:*** *Basic demographic information will be recorded such as your age and gender. Standard parameters from your eye examinations such as vision, eye pressure and the number of medications you take will be recorded. Any complications or changes to your glaucoma treatment will also be recorded. You will take a questionnaire before the surgery and a questionnaire after the surgery to see how you glaucoma and the procedure has affected you.*

- ***What are the types of activities you will do in the research:*** *You will have routine follow up visits with your eye surgeon to monitor the healing process, vision, eye pressure and eye health.*
- ***In what ways is this research novel:*** *This study assesses how the microstent affects your quality of life, rather than just looking at the medical effectiveness.*

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have visually significant cataract and mild-to-moderate primary open angle glaucoma, and you are planning to have cataract surgery with a Hydrus Microstent. The purpose of this research study is to assess the effect of the Hydrus microstent on quality of life.

The Hydrus microstent is approved by the U.S. Food and Drug Administration (FDA). It has been studied in multiple clinical studies and is used by ophthalmologists to help control intraocular pressure. We don't know enough about how it affects the quality of life of those who are treated with the microstent. We will use questionnaires before and after surgery to collect response by all the study subjects and analyze that information.

About 38 subjects will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will take the same number of office and surgery visits as if you were not involved in the study. The timeline is explained below.

1. Initiation Visit:

Before any study-related tests and procedures are performed, you will be asked to read, sign and date this consent document. In order to determine if you qualify to take part in this study, the following will be assessed:

- Review of ocular history, vision and eye examination including gonioscopy, intraocular pressure measurement, and assessment of the health of the ocular surface. To qualify for the study, you need to have mild to moderate open-angle glaucoma and visually significant cataracts in both eyes.
- If you qualify to take part in this study, you will then participate in the pre-surgery questionnaire and be scheduled for cataract surgery with Hydrus microstent in both eyes, approximately two weeks apart.

2. First surgery:

- Your cataract surgery with Hydrus microstent will be done according to routine medical care at Fresno Surgical Hospital as an outpatient.

3. Day 1 surgery follow-up first eye:

- Postoperative Day 1 visit for first eye—Check vision, slit lamp examination and eye pressure.

4. Second surgery:

- Your cataract surgery with Hydrus microstent will be done according to routine medical care at Fresno Surgical Hospital as an outpatient.

5. Day 1 surgery follow-up second eye:

- Postoperative Day 1 visit for second eye—Check vision, slit lamp examination and eye pressure.

6. Week 3-4 follow up:

- Postoperative Week 3-4 visit after second eye surgery—Measure for glasses if needed; check slit lamp examination and eye pressure.

7. Month 3-4 follow up:

- Postoperative Month 3-4 visit—Check vision, slit lamp examination and eye pressure; take the post-surgery questionnaire.

After Study Treatment:
After the study is over, you will continue routine care with your eye surgeon or the original referring provider for your glaucoma care.

EXPECTATIONS
If you participate in this study, you will be expected to:

- Follow the study doctor's instructions for completing study procedures.
- Be able to complete the pre-surgery and post-surgery questionnaires.

RISKS OF STUDY PARTICIPATION

- Risks of the cataract surgery are listed separately in the cataract surgery consent form you will sign as part of your routine medical care. The risks of the Hydrus microstent will be discussed with you by your treating physician, and are part of your routine medical care. Participating in this study does not change the risks of the cataract surgery with the Hydrus microstent. Cataract surgery with Hydrus Microstent is being recommended regardless of whether or not you decide to participate in this study. The study does not alter the care you are receiving or the risks associated with that care.
- As long as you follow the recommended study visit schedule or any other visits that could be recommended by your eye surgeon, your glaucoma will be cared for in the normal way and according to the normal clinical principles for managing the disease.
- You will be asked about your quality of life in the study questionnaires. It is possible that some of the questions may be upsetting.

ALTERNATIVES TO PARTICIPATION
You do not have to be in this study to receive treatment for your cataracts and glaucoma. The alternative is to not participate in this study. You will still undergo cataract surgery and microstent placement if you choose not to participate in the study, but you will not need to do questionnaires before and after treatment.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS
You may or may not benefit as a result of your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION
You will be paid up to a total of **$200** if you complete this study in its entirety. You will be paid for the visits where you complete the questionnaires, according to the following schedule:

- $100 for the Initiation Visit
- $100 for Month 3-4 Follow-up Visit

You will be paid shortly following each of the visits indicated.

If you have any questions regarding your compensation for participation, please contact the study staff.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- A limited number of representatives from the study sponsor (namely its monitors and auditors),
- The research ethics review board – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study subjects),

- Government regulatory authorities including Health Canada, the U.S. Food and Drug Administration (FDA) and other foreign regulatory agencies.

Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing and dating this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

COMPENSATION FOR INJURY
If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

If you are injured as a result of the cataract surgery or microstent placement, your medical insurance should cover any expense since both the cataract surgery and Hydrus microstent placement are approved standard of care treatments. Your study doctor and the sponsor of the study have no plans to provide compensation for any injury or harm resulted by the eye surgery performed by the eye surgeon, study doctor and/or study staff. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

COSTS
There will be no cost) for your participation in this study. The study-related procedures and study visits will be covered by your insurance as standard of care, according to the terms of your specific medical insurance.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:

  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00069681.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ (if applicable)

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your regular doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- The study doctor and study staff.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ
(if applicable)
The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date