**Sponsor:** Eye Center of North Florida

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**Title:**

**A Prospective Study to Evaluate the Raindrop® Near Vision Inlay in Presbyopes Implanted in Corneal Pockets with a Delayed or Non-Delayed Approach**

The signature of the Investigator below constitutes his approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations stated in the protocol. It is also agreed that that the study will not be initiated without the approval of an appropriate Institutional Review Board (IRB).

Bret L. Fisher, MD

Printed Name of Investigator

9/25/2017

Date

Signature of Investigator

# A Prospective Study to Evaluate the Raindrop Near Vision Inlay in Presbyopes Implanted in Corneal Pockets with a Delayed or Non-Delayed Approach

## Protocol Number, ECNF17-001

## 1 Principal Investigator: Bret L. Fisher, MD

### 1.1 Practice Name and Address:

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## 2 Objective

2.1 The objective of this study is to evaluate the Raindrop® Near Vision Inlay for the improvement of near vision in presbyopes implanted in corneal pockets with a delayed or a non-delayed approach. Patients must be presbyopic with a reading add from +1.5 to +2.5 D, and both emmetropes (MRSE from -0.5 to +0.5 D) as well as ametropes (requiring concurrent LASIK) are included in the investigation. In the non-delayed approach, the corneal pocket is created and inlay implanted on the same surgical day. In the delayed approach, the corneal pocket is created and dissected but the corneal inlay is not implanted. After one to three months, the corneal inlay is implanted on a second surgical day. The clinical outcomes will be statistically analyzed to determine safety and efficacy. Efficacy outcomes include monocular and binocular visual acuity at near and distance. Safety outcomes include corrected distance visual acuity, central corneal haze, applanation intraocular pressure, and optical coherence tomography. Clinical parameters will be measured according to the schedule in Appendix A.

## 3 Study Variables to be Evaluated:

### 3.1 Uncorrected Visual Acuity

Hypothesis: After the inlay procedure, patients will attain functional near acuity in the inlay eye and functional distance vision binocularly.

### 3.2 Incidence of Corneal Reaction

Hypothesis: Patients implanted with a delayed approach will have minimal incidence of corneal reaction as compared with non-delayed implantation.

## 4 Study Design

The study will be a prospective, multicenter, open label clinical trial where a maximum of 30 non-dominant eyes are implanted with the Raindrop Near Vision Inlay. Each surgical site will be responsible for assigning patients to either the delayed or the non-delayed groupings. The patient population for this study is presbyopic (ADD from +1.5 to +2.5 D), and includes both emmetropes (MRSE from -0.5 and +0.5 D) as well as ametropes in need of LASIK distance vision correction. Eligible patients who are interested in participating and have provided their informed consent will be examined preoperatively. Baseline measurements will include ocular dominance, pupil size, slit lamp assessment, manifest refraction, uncorrected and best-corrected visual acuity, central keratometry, optical coherence tomography, and applanation intraocular pressure.

Suitable patients who provide informed consent will undergo implantation of the Raindrop inlay in the non-dominant eye. If LASIK is necessary to correct ametropia, the surgical procedure will first create a corneal pocket, then a corneal flap using a femtosecond laser. The flap will be fully lifted and excimer laser ablation will be performed. After excimer laser ablation, the corneal pocket will be dissected using a surgical spatula. If the patient is emmetropic and LASIK is not necessary, the surgical procedure will only create a corneal pocket. In the non-delayed approach, the inlay will be delivered

inside the pocket and centered on the light constricted pupil during the same procedure. In the delayed approach, the corneal inlay will be implanted in one to three months during a second surgical procedure. All patients will follow a three-month steroid regimen after corneal inlay implantation.

4.1 **Study Population:**

4.1.1 Maximum of 30 patients (sites assign to delayed or non-delayed groupings).

4.2 **Inclusion Criteria:**

4.2.1 Patients require a near reading add from +1.5 to +2.5 D in the non-dominant eye.

4.2.2 Patients have a photopic pupil size of at least 3.0 mm in the non-dominant eye.

4.2.3 Patients have a central corneal thickness ≥ 500 microns in the non-dominant eye.

4.2.4 Patients have corrected distance and near visual acuity of 20/25 or better in each eye.

4.2.5 Patients have uncorrected near acuity of 20/40 or worse in the non-dominant eye.

4.2.6 Patients are willing and able to understand and sign a written Informed Consent Form prior to any study-specific procedures.

4.2.7 Patients are willing and able to return for scheduled follow-up examinations for 24 months after corneal inlay implantation.

4.3 **Exclusion Criteria**

4.3.1 Patients with clinically significant dry eye (i.e., significant diffuse punctate staining with fluorescein and a tear breakup time less than 8 s) in either eye.

4.3.2 Patients with a planned corneal residual bed thickness that is less than 300 microns (corneal thickness - (intended ablation depth + intended flap thickness)).

4.3.3 Patients with macular pathology based on dilated fundus exam and/or optical coherence tomography (OCT) image.

4.3.4 Patients who would be co-managed by an ophthalmologist or optometrist who is not approved as a ReVision Optics investigator.

4.3.5 Patients with ocular pathology or disease (including pupil pathology such as fixated pupils) that might confound the outcome or increase the risk of adverse event.

4.3.6 Patients taking systemic or topical medications that might confound the outcome or increase the risk of adverse event. Patients taking isotretinoin or amiodarone hydrochloride and any other medication that affects the tear film or accommodation, including but not limited to, mydriatic, cycloplegic and mitotic agents, tricyclic, phenothiazines, benzodiazepines, and first generation antihistamines.

4.3.7 Patients with known sensitivity to any planned study medications.

4.3.8 Patients with residual, recurrent, active or uncontrolled eyelid disease.

4.3.9 Patients with significant corneal asymmetry or irregular topography.

4.3.10 Patients with clinically significant anterior segment pathology.

4.3.11 Patients with any corneal abnormality, including but not limited to, slit lamp findings for corneal staining Grade 3 or higher, recurrent corneal erosion or severe basement membrane disease, and pterygium extending onto the cornea.

4.3.12 Patients with ophthalmoscopic/topographic signs of keratoconus or those who are keratoconus suspect.

4.3.13 Patients with history of Herpes zoster or Herpes simplex keratitis.

4.3.14 Patients with any progressive retinal disease or patients with a history or evidence of retinal vascular occlusion and/or hypercoagulability, because of the risks associated with high pressures during suction application.

4.3.15 Patients with known history of steroid-responsive intraocular pressure increases, glaucoma, preoperative IOP > 21 mm Hg, or are otherwise suspected of having glaucoma.

4.3.16 Patients with amblyopia or strabismus or those who are at risk for developing strabismus postoperatively as determined by corneal light reflex and cover-uncover testing.

4.3.17 Patients with diabetic retinopathy, collagen, vascular, diagnosed autoimmune disease (e.g., lupus, rheumatoid arthritis, fibromylagia), immunodeficiency (e.g., HIV), connective tissue disease, or clinically significant atopic syndrome such as allergies or asthma.

4.3.18 Patients on chronic systemic corticosteroid or other immunosuppressive therapy that may affect wound healing.

4.3.19 Patients with any type of active cancer (ophthalmic or non-ophthalmic).

4.3.20 Patients with uncontrolled infections of any kind.

4.3.21 Patients who are pregnant, lactating, of child-bearing potential and not practicing a medically approved method of birth control, or planning to become pregnant during the course of the trial, and patients with other conditions associated with fluctuation of hormones that could lead to refractive changes.

4.3.22 Patients who actively participate in contact sports (i.e., boxing, martial arts) where impacts to the face and eye are a normal occurrence.

4.3.23 Patients participating in any other ophthalmic or non-ophthalmic drug/device clinical trials during the time of this clinical investigation.

## 4.4 Clinical Parameters

4.4.1 Refer to Appendix A.

## 4.5 Examination Schedule

Patients will be examined and evaluated according to the following schedule of visits:

Preoperative Evaluation (Day -90 to Day -1)

Operative Evaluation (Day 0)

Day 1 (1 to 2 days post-implant)

1 Week (5 to 9 days post-implant)

1 Month (3 to 6 weeks post-implant)

3 Months (10 to 14 weeks post-implant)

6 Months (20 to 26 weeks post-implant)

12 Months (11 to 14 months post-implant)

18 Months (16 to 20 months post-implant)

24 Months (22 to 26 months post-implant)

Other visits may be added to monitor patient progress.

4.6 **Surgical Procedure:**

The surgical procedure for implanting the corneal inlay in the non-dominant eye for the improvement of near vision is outlined as follows:

Non-Delayed Approach (Single Surgery):

4.6.1 Prepare the non-dominant eye for surgery. Give the patient topical analgesic.

4.6.2 Place the patient with the non-dominant eye under the surgical microscope.

4.6.3 Carefully drape the patient's eye lashes with surgical tape and place a lid speculum (vacuum speculum preferred) into the appropriate position.

4.6.4 If LASIK distance vision correction is necessary, using a femtosecond laser, create a corneal pocket targeting a depth of at least 80 microns below the corneal flap + assumed stromal ablation. Then create a corneal flap (depth 90 - 110 microns). Lift and retract the resultant flap completely to the hinge. Perform the LASIK treatment to maximize distance vision according to standard surgical practice. Fully dissect the pocket with an appropriate surgical instrument, and irrigate inside with BSS. For inlay preparation and delivery, proceed to section 4.6.6.

4.6.5 If LASIK distance correction is not necessary, using a femtosecond laser, create a corneal pocket at 30% of central corneal thickness. If the patient had a previous LASIK procedure, then create the pocket at least 80 microns below the previous corneal flap. Fully dissect the pocket with an appropriate surgical instrument and irrigate inside with BSS. For inlay preparation and delivery, proceed to section 4.6.6.

4.6.6 Prepare the Raindrop corneal inlay delivery device. Use injectable fluorescein to stain and visualize the inlay.

4.6.7 Once ready, insert the delivery device into the fluid filled pocket cavity and gently sweep the inserter until the inlay is delivered.

4.6.8 Move the inlay to the center of the pupil by employing an appropriate surgical tool to gently push the inlay into position.

4.6.9 Remove the lid speculum, and conduct a slit lamp examination to ensure that the inlay is well centered.

4.6.10 Administer a single drop of non-BAK preserved antibiotics and steroids. Insert bandage contact lens upon investigator discretion.

4.6.11 Carefully instruct the patient on the postoperative medication regimen.

4.6.12 Prior to discharging the patient, place a shield on the non-dominant eye.

Delayed Approach (Two Surgeries):

4.6.13 Prepare the non-dominant eye for surgery. Give the patient topical analgesic.

4.6.14 Place the patient with the non-dominant eye under the surgical microscope.

4.6.15 Carefully drape the patient's eye lashes with surgical tape and place a lid speculum (vacuum speculum preferred) into the appropriate position.

4.6.16 If LASIK distance vision correction is necessary, using a femtosecond laser, create a corneal pocket targeting a depth of at least 80 microns below the corneal flap + assumed stromal ablation. Then create a corneal flap (depth 90 - 110 microns). Lift and retract the resultant flap completely to the hinge. Perform the LASIK treatment to maximize distance vision according to standard surgical practice. Fully dissect the pocket with an appropriate surgical instrument.

4.6.17 If LASIK distance correction is not necessary, using a femtosecond laser, create a corneal pocket at 30% of central corneal thickness. If the patient had a previous LASIK procedure, then create the pocket at least 80 microns below the previous corneal flap. Fully dissect the pocket with an appropriate surgical instrument.

4.6.18 Remove the lid speculum, Administer a single drop of non-BAK preserved antibiotics and steroids. Insert bandage contact lens upon investigator discretion.

4.6.19 Carefully instruct the patient on the postoperative medication regimen.

One to Three Months after Pocket Creation

4.6.20 Prepare the non-dominant eye for surgery. Give the patient topical analgesic.

4.6.21 Place the patient with the non-dominant eye under the surgical microscope.

4.6.22 Carefully drape the patient's eye lashes with surgical tape and place a lid speculum (vacuum speculum preferred) into the appropriate position.

4.6.23 Find pocket incision and mark it. Fully dissect the pocket with an appropriate surgical instrument and irrigate inside with BSS.

4.6.24 The nurse/technician should prepare the Raindrop corneal inlay delivery device. Use injectable fluorescein to stain and visualize the inlay.

4.6.25 Once ready, insert the delivery device into the fluid filled pocket cavity and gently sweep the inserter until the inlay is delivered.

4.6.26 Move the inlay to the center of the pupil by employing an appropriate surgical tool to gently push the inlay into position.

4.6.27 Remove the lid speculum, and conduct a slit lamp examination to ensure that the inlay is well centered.

4.6.28 Administer a single drop of non-BAK preserved antibiotics and steroids. Insert bandage contact lens upon investigator discretion.

4.6.29 Carefully instruct the patient on the postoperative medication regimen.

4.6.30 Prior to discharging the patient, place a shield on the non-dominant eye.

### 4.7 Concomitant Medications

All medications specified in this section will be administered for the non-dominant eye implanted with the corneal inlay. These medications include:

- BSS Sterile Irrigating Solution, 15 ml (balanced salt solution, Alcon)
- Non-preserved artificial tears (e.g. carboxymethylcellulose sodium 0.5%)
- Topical anesthetic
- Non-BAK preserved antibiotic (e.g. moxifloxican hydrochloride 0.5%))
- Non-BAK preserved steroid (e.g., dexamethasone 0.1%)
- Low dose steroid (e.g., loteprednol etabonate 0.5%)

#### 4.7.1 Preoperative Medications

The following medications should be used preoperatively in the non-dominant eye:

- Day prior to surgery, the patient should administer 1 drop of non-preserved artificial tears four times per day and 1 drop of non-BAK preserved strong steroid four times per day.
- Night prior to surgery, the patient should administer 1 drop of non-BAK preserved antibiotic.

#### 4.7.2 Perioperative Medications

The following medications should be used perioperatively:

- Non-BAK preserved antibiotics: 1 drop in the non-dominant eye 20 minutes prior to surgery.
- Non-BAK preserved strong steroid: 1 drop in the non-dominat eye 20 minutes prior to surgery.
- Topical anesthetic: 2-3 drops of anesthesia in non-dominant eye during surgery.
- BSS Sterile Irrigating Solution: Sufficient drops to extensively irrigate cornea.

#### 4.7.3 Post-Implant Medications

The following medications should be used after corneal inlay implantation (any deviation will require prior authorization):

- Non-BAK preserved antibiotics:
  - Days 1-7: four times per day
- Non-BAK preserved strong steroid:
  - Days 1-7: four times per day
  - Days 8-14: three times per day
  - Days 15-21: two times per day
  - Days 22-28: once per day
- Non-BAK preserved mild steroid:
  - Days 29-59: two times per day
  - Days 60-90: one time per day
- Non-preserved artificial tears:
  - As needed

## 5 APPENDICES

### 5.1 Appendix A: Schedule of Visits and Parameters

Appendix A

Schedule of Visits and Parameters

| Visits | Preop | 1D | 7D | 1M | 3M | 6M | 12M | 18M | 24M |
|---|---|---|---|---|---|---|---|---|---|
| Optical Coherence tomography | | | | | | | | | |
| Implanted Eye | X | | | X | X | X | X | X | X |
| Fellow Eye | X | | | | | | X | | X |
| Oculus Pentacam | | | | | | | | | |
| Implanted Eye | X | | | X | X | X | X | X | X |
| Fellow Eye | X | | | | | | X | | X |
| UDVA (6 m) & UNVA (40 cm) | | | | | | | | | |
| Implanted Eye | X | | X | X | X | X | X | X | X |
| Fellow Eye | X | | | | | | X | | X |
| Binocular | X | | | X | X | X | X | X | X |
| Manifest Refraction | | | | | | | | | |
| Implanted Eye | X | | | X | X | X | X | X | X |
| Fellow Eye | X | | | | | | X | | X |
| CDVA (6 m) | | | | | | | | | |
| Implanted Eye | X | | | X | X | X | X | X | X |
| Fellow Eye | X | | | | | | X | | X |
| IOP (applanation tonometer) | | | | | | | | | |
| Implanted Eye | X | | | X | X | X | X | X | X |
| Fellow Eye | X | | | | | | X | | X |
| Corneal pachymetry | | | | | | | | | |
| Implanted Eye | X | | | | | | X | | X |
| Fellow Eye | X | | | | | | X | | X |
| photopic pupil size | | | | | | | | | |
| Implanted Eye | X | | | | | | | | |
| Fellow Eye | X | | | | | | | | |
| Slit lamp examination | | | | | | | | | |
| Implanted Eye | X | X | X | X | X | X | X | X | X |
| Fellow Eye | X | | | | | | X | | X |
| Concomitant medications | X | X | X | X | X | X | X | X | X |
| Complications/Adverse Events | | X | X | X | X | X | X | X | X |

EXHIBIT B

## BUDGET

The Clinical Site has agreed to implant the commercially available ReVision Optics Raindrop Near Vision inlay in up to 30 patients per protocol recommendations, and to collect clinical results on each patient from the pre-operative visit through the 24 months postoperative follow-up. The budget, per patient, is included below:

**Compensation to Clinical Site (per patient, maximum of 30)**

| | |
|---|---|
| Marketing | $300 |
| Patient Set-Up | $300 |
| Preoperative | $250 |
| Medications | $150 |
| Laser Access Fee | $300 |
| Operative | $250 |
| 1 Month Post-Op | $250 |
| 3 Months Post-Op | $250 |
| 6 Months Post-Op | $250 |
| Patient Incentive | $100 |
| 12 Months Post-Op | $250 |
| 18 Months Post-Op | $250 |
| Patient Incentive | $100 |
| 24 Months Post-Op | $250 |

Additional Support: No Charge Product (Raindrop Near Vision Inlay) provided by ReVision Optics. Grant for IRB Related Activities, up to $4,500. Support for Medical Writer for Journal, up to $5,000. Grant for travel for podium presentations, up to $10,000.

## PAYMENT

**The study grant will be provided in 5 installments based on completion of the milestones included below.**

**Grant 1, $11,700**- Study Start Up
**Grant 2, $23,400**- 50% Enrollment (50% of the maximum number of study patients enrolled, i.e., 20)
**Grant 3, $29,250**- 100% Enrollment (i.e. up to 40 patients)

**Grant 4, $23,400**- 50% Data Capture (i.e., 1-year follow-up data for 100% of study patients have been captured)
**Grant 5, $29,250**- 100% Data Capture, Study Completion

For Grants 2, 3, and 4, Clinical Site will provide milestone reports to ReVision Optics summarizing study results in a report format mutually agreed to by the Clinical Site and ReVision Optics. Upon ReVision Optics confirmation that each report has been received, and the appropriate milestone achieved, the amount due will be paid via wire transfer or check.
For Grant 5, Clinical Site will provide ReVision Optics with a complete data set in a format mutually agreed by Clinical Site and ReVision Optics. Upon ReVision Optics confirmation that the data set has been received, and the appropriate milestone achieved, the amount due will be paid via wire transfer or check.

If the total amount paid to Clinical Site pursuant to the Agreement exceeds Clinical Site's actual Study costs (calculated as described in this Budget), Clinical Site agrees to return any excess funds to ReVision Optics.

## PREAMBLE

What follows is a discussion intended to assist physicians who are implanting the Raindrop near vision inlay who may be asked by a prospective patient who is a pilot how that would affect their ability to fly. Beyond the clinical issue of vision with the inlay, there are special issues unique to pilots, in terms of medical certification and fitness to fly that may affect their decision to have the Raindrop procedure. Any pilot who has questions regarding the legal or regulatory issues surrounding implantation of the Raindrop near vision inlay should be advised that it remains their responsibility to obtain appropriate legal counsel or FAA guidance for their particular situation.

## BACKGROUND

The Federal Aviation Administration, among their other responsibilities, is tasked with developing, promulgating, and maintaining standards for the certification, including medical certification, of civilian pilots (also called "airmen") in the United States. As part of this duty, they provide general guidelines or rules regarding specific medical issues, and also make determinations concerning individual airmen's fitness through the use of specially trained physicians known as Aviation Medical Examiners. Pilots may obtain different ratings, allowing them to fly in different capacities (e.g. for personal recreation, for hire, or as the pilot of larger aircraft transporting many people for the airlines). The medical requirements and standards, including those for vision, often vary between these different categories of pilot ratings, and thus there may be different guidance given to a prospective patient depending on their type of flying and individual circumstances.

## DISCUSSION

Vision is a critical need for those engaged in piloting an aircraft, whether for personal recreation, or as the pilot of a large commercial airliner. Therefore, any disturbance, perturbation, or deficit in the visual system may adversely impact an individual's ability to safely perform his or her duties as a pilot. Uncorrected refractive error, cataracts, and presbyopia are common conditions affecting pilots and their vision. Treatment for these conditions may restore an individual's vision and improve their visual functioning as a pilot, but may also be associated with temporary or permanent side effects which may be problematic or associated with safety risks to the pilot and/or their passengers. The Raindrop near vision inlay is indicated for the improvement of uncorrected near vision in the non dominant eye of patients with presbyopia with a refraction of -0.50 to +1.00 with 0.75 diopter or less of astigmatism.

The FAA has developed and promulgated standards for airmen with cataracts undergoing cataract surgery with monofocal, multifocal, and accommodative lens implants. They have also developed and promulgated standards for airmen who have received LASIK and PRK to correct refractive error. Standards also exist for pilots who choose to fly with multifocal contact lenses for the correction of presbyopia. Interestingly, while monovision type corrections are allowed for both cataract surgery and laser vision correction, after a period of adaptation, and a subsequent flight test of the airman, monovision contact lenses are not allowed. To date, no standards, rules, or opinions have been officially put forth by the FAA on medical certification of airmen who have received corneal inlays

for the correction of presbyopia, either alone or in combination with LASIK. Therefore, definitive guidance cannot be offered regarding these patients; however, some inferences can be drawn from the rules regarding LASIK and presbyopia correcting IOLS, and recent actions by the FAA in a particular case.

For cataract surgery with a monofocal IOL, the FAA requires that an airman refrain for flying for one month after surgery. In the case of multifocal IOLs, this period is extended to three months, presumably to allow for neuroadaptation, which can take longer in patients with multifocal IOLs. Patients with multifocal contact lenses have a one month prohibition from flying. There is no period of "grounding" after LASIK or PRK. After cataract surgery or laser vision correction, the airman must obtain a completed FAA form 8500-7 "Report of Eye Evaluation" from their treating provider, and this document must state that the airman has stable visual acuity, no significant side effects or complications, no problems with glare or flares, and no other visual phenomena adversely affecting the airman's visual performance. Of note, patients opting for monovision correction with either lens implants or laser vision correction are subject to a six month adaptation period during which glasses must be worn for distance for the near eye while flying, subsequent to which the airman must undergo a medical flight test before being allowed to resume their privileges as a pilot in command of an aircraft without glasses.

After cataract surgery with any type of IOL or multifocal contact lens, or after laser vision correction, the airman must meet the visual standards, as required for each class, in each eye. For commercial or airline transport pilots 20/20 distance vision with or without correction is generally required in each eye, while for recreational pilots the standard is 20/40 for distance. For near, measured at 16 inches, the standard is 20/40 with or without correction for all classes. For intermediate, there is no requirement for third class (recreational/private) pilots, but commercial or airline pilots must have 20/40 or better in each eye separately, with or without correction at age 50 and over, as measured at 32 inches.

Recently, an optometrist in Tucker, Georgia reported that a patient of hers who had received the Raindrop near vision inlay, was advised by his AME preoperatively of the need to meet the visual standards for his class of certification following surgery, but made no mention of any period of grounding. Following the procedure, good vision was obtained, and the required paperwork was filed with the FAA. However, the FAA then made the decision to ground the pilot for 90 days. This suggests either that the FAA has decided to apply the standard for a multifocal IOL to corneal inlay patients, or that in this case they did not recognize or understand the nature of the patient's procedure. Whether their decision was fair or appropriate in this instance is a subject for debate, but the lack of a clear national policy by the FAA on FDA approved corneal inlays for presbyopia correction is certainly something that remains to be addressed.

## CONCLUSION

No formal guidance exists from the FAA regarding the use of corneal inlays such as the Raindrop near vision inlay in civilian pilots. Lacking standards, practitioners implanting the Raindrop should discuss with their patients who are pilots the uncertainty surrounding medical certification after the

procedure and the possibility of being grounded for 90 days, despite good visual results. As with any other ocular surgery, pilot patients should also be counseled that they will need to continue to meet the visual standards for their class. Because other types of correction of presbyopia are allowed by the FAA, such as multifocal contact lenses and lens implants, there is no reason to believe that corneal inlays would not be allowable or would be prohibited. Finally, the visual benefit of the Raindrop near vision inlay would be expected to be as valuable to pilot patients as to non-pilot patients, and there is nothing in the literature or current experience to suggest that it would be detrimental in any way in the operation of an aircraft.

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