



#### CAUTION

Federal law restricts this device to sale by or on the order of a physician. Refer to Professional Use Information for additional discussions on risks, benefits, alternatives, and results of the study conducted to support FDA approval.

#### CAUTION

Federal law restricts this device to practitioners who have been trained and have experience in the surgical management and treatment of refractive errors.

#### DESCRIPTION

The Raindrop Near Vision Inlay is a biocompatible hydrogel corneal inlay. It is designed to be implanted under a femtosecond laser flap onto the stromal bed of the cornea, centered over a light-constricted pupil. The Raindrop Near Vision Inlay reshapes the central region of the cornea to provide a zone of increased power for focusing on near objects, resulting in improvement in near vision. The Raindrop Near Vision Inlay is supplied steam sterilized and pre-loaded in its delivery device, the Inlay Inserter. It is for single-use only.

#### INDICATIONS FOR USE

The Raindrop Near Vision Inlay is indicated for intrastromal implantation to improve near vision in the non-dominant eye of phakic, presbyopic patients, 41 to 65 years of age, who have manifest refractive spherical equivalent (MRSE) of +1.00 diopters (D) to -0.50 D with less than or equal to 0.75 D of refractive cylinder, who do not require correction for clear distance vision, but who do require near correction of +1.50 D to +2.50 D of reading add.

#### DETAILED DEVICE DESCRIPTION

The Raindrop Near Vision Inlay is a round, meniscus-shaped corneal inlay (**Figure 1**).

Raindrop Near Vision Inlay Properties:

- Inlay Material: Optically clear hydrogel<sup>1</sup>
- Refractive Power: None<sup>1</sup>
- Diameter: 2 mm<sup>1</sup>
- Center Thickness: 32 µm<sup>1</sup>
- Index of Refraction: 1.37<sup>1</sup>
- Visible Light Transmittance: 99.7%<sup>1</sup>
- Water Content: 77%<sup>1</sup>
- Range of Percent Change in Concentration of Glucose in the Cornea Due to the Inlay (estimated by modeling): -2.5% in tissue anterior to the inlay to +0.6% in tissue just posterior to the inlay<sup>2</sup>
- Range of Percent Change in Concentration of Oxygen in the Cornea Due to the Inlay (estimated by modeling): +3.3% in tissue just anterior to the inlay to -3.5% posterior to the inlay<sup>2</sup>

#### PACKAGE CONTENTS

One (1) Raindrop Near Vision Inlay preloaded in Inlay Inserter delivery device

One (1) Blunt Tip Cannula
One (1) 5 mL Syringe
One (1) Instructions For Use
One (1) Patient Information Card
Four (4) Serial Number Stickers

#### HOW SUPPLIED

Each Raindrop Near Vision Inlay is supplied steam sterilized. The vial containing the Raindrop Near Vision Inlay should be stored at room temperature and opened only under sterile conditions.

#### CAUTION

Do not use the Raindrop Near Vision Inlay if the package has been damaged. The sterility of the Raindrop Near Vision Inlay may have been compromised.

#### USE-BY DATE

The use-by date on the Raindrop Near Vision Inlay package is the sterility expiration date. The Raindrop Near Vision Inlay should not be implanted after the indicated sterility use-by date.

#### CONTRAINDICATIONS

The Raindrop Near Vision Inlay is contraindicated in patients who:

- have a corneal thickness that does not allow for a minimum of 300 microns of stromal bed thickness below the flap;
- have an abnormal corneal topographic map of the eye to be implanted;
- have an active eye infection or active inflammation;
- have active autoimmune or connective tissue diseases;
- have severe dry eye syndrome;
- have keratoconus or are a keratoconus suspect;
- have a recent herpes eye infection or problems resulting from a previous infection;
- have uncontrolled diabetes; or
- have uncontrolled glaucoma.

#### WARNINGS

The Raindrop Near Vision Inlay may not be suitable for patients who:

- have dry eye syndrome, which may worsen following Raindrop Near Vision Inlay implantation;
- have past herpetic corneal infection, which might increase the risk of corneal infections;
- have controlled glaucoma, including a history of a rise in eye pressure due to steroids, which may worsen with steroid use following Raindrop Near Vision Inlay implantation;
- have controlled connective tissue disease or autoimmune disease, which may affect the epithelial remodeling effect Raindrop Near Vision Inlay induces or wound healing;
- have controlled diabetes, which may affect wound healing following Raindrop Near Vision Inlay implantation;
- have a weakened immune system due to medications (e.g., steroids) or medical conditions (e.g., Acquired Immunodeficiency Syndrome), which may make a patient more prone to infection after surgery. Such medications and conditions may increase the risk for other complications, such as dry eye or abnormal wound healing;
- are taking isotretinoin which may cause changes to patients' vision following Raindrop Near Vision Inlay implantation;
- are taking chronic medications known to worsen or cause severe dry eye. These medications may include anti-histamines, beta-blockers, birth control pills, diuretics, drugs for the treatment of cardiac arrhythmia, or other medications which may worsen dryness symptoms and signs after implantation of the Raindrop Near Vision Inlay;
- have any corneal dystrophy or corneal degeneration that may worsen and decrease vision following Raindrop Near Vision Inlay implantation;
- have macular degeneration, retinal detachment, cataract, or any other disease that would compromise vision and prevent patients from experiencing an improvement in near vision following implantation of the Raindrop Near Vision Inlay;
- have an irreversible decrease in vision in either eye, e.g., resulting from amblyopia, injury, disease, or other abnormality which might prevent the patient from experiencing an improvement in near vision following implantation of the Raindrop Near Vision Inlay;
- have a significant change in distance manifest refraction, i.e., a change in distance vision or manifest refraction of more than 0.50 D in the previous 12 months;

- have uncorrected near visual acuity of 20/40 or better or 20/200 or worse in the non-dominant eye, uncorrected distance visual acuity worse than 20/25 in each eye, and distance and near visual acuities that do not correct to at least 20/20 in each eye;
- do not demonstrate monovision tolerance by contact lens trial in the non-dominant eye for at least five (5) days;
- have a cornea less than 500 µm thick that will not allow for a minimum femtosecond laser flap depth of 30% and a minimum of 300 µm of residual posterior stromal bed thickness to safely perform the procedure;
- have a manual microkeratome created flap, because the stromal bed may not be uniform in depth and smooth;
- have a photopic pupil size of ≤ 3.0 mm or a mesopic pupil size ≥ 7.0 mm, as distance vision may be adversely compromised;
- participate in activities that could damage the flap or dislodge the inlay, such as contact sports, like football or martial arts;
- or have a habit of extreme and frequent eye rubbing which may cause the Raindrop Near Vision Inlay or flap to misalign.

#### PRECAUTIONS

- If the Raindrop Near Vision Inlay becomes dislodged from the Inlay Inserter prior to placement on the stromal bed, return the vial to ReVision Optics, Inc., and prepare a new Raindrop Near Vision Inlay for implantation.

- Do not implant the Raindrop Near Vision Inlay under a femtosecond laser flap shallower than 30% of the central corneal thickness.
- Do not use the Raindrop Near Vision Inlay if primary package has been damaged or broken.
- Do not resterilize the Raindrop Near Vision Inlay, as it may become damaged.
- Do not reuse the Raindrop Near Vision Inlay, as it may cause infection or cross-contamination.
- If a patient is wearing contact lenses to correct near vision, then the use of the contact lens should be discontinued and topographic and refractive stability confirmed prior to determining whether the patient is an appropriate candidate for Raindrop Near Vision Inlay implantation prior to undergoing surgery. Hard or rigid gas-permeable contact lens wearers must not have worn their lenses for at least one (1) week prior to the preoperative evaluation in the eye to be implanted. Contact lens wearers should exhibit a stable refraction at two (2) examinations that are at least seven (7) days apart. A stable preoperative refraction is defined as when the manifest refractive spherical equivalent and topography measurements (i.e., average central keratometric measurements) obtained at the first visit does not differ by more than 0.50 D from the respective measurements taken at the second visit.
- Patients should be instructed not to rub their eyes, wear eye make-up, play contact sports, exercise, swim, garden, smoke, or sustain exposure to dusty environments for at least the first week following Raindrop Near Vision Inlay implantation.
- Some patients may experience a delayed recovery of best-corrected visual acuity during the postoperative period. This is usually mitigated through the use of aggressive dry eye treatment.
- The safety and effectiveness of Raindrop Near Vision Inlay implantation in conjunction or in sequence with LASIK or other refractive procedures is not known.
- The safety and effectiveness of cataract extraction with intraocular lens implantation after Raindrop Near Vision Inlay implantation is not known.
- Removal of the inlay may be necessary prior to any retinal or vitreal procedures or prior to laser procedures due to potential difficulty with viewing and/or delivering the appropriate laser energy or other treatment to the desired target tissue through the Raindrop Near Vision Inlay. In addition, with the exception of Nd-YAG bench testing on the inlay, the safety of laser procedures or other treatments involving delivery of energy through the inlay have not been investigated.

While the following is a potential risk, it is not known whether the Raindrop Near Vision Inlay causes the following adverse event since it was not studied:

- it is unknown whether stereoacuity is affected by implantation of the device since this was not investigated in the clinical trial.

- The safety and effectiveness of the Raindrop Near Vision Inlay has NOT been established in:
- patients who are pregnant or currently nursing;
  - patients with active/recurrent blepharitis;
  - patients with anesthetized Schirmer’s test results of less than 10 mm of wetting, or tear break-up times of less than eight (8) seconds, or the presence of greater than mild symptoms of dryness or discomfort, and patients with slit lamp findings of corneal staining with sodium fluorescein or rose bengal;
  - patients who have worn RGP or PMMA contact lenses in the last three (3) weeks or soft contact lenses within one (1) week prior to preoperative examination;
  - patients with corneal endothelial cell counts of < 2000 cells/mm<sup>2</sup>;
  - patients with previous eye surgeries, including refractive surgery, such as PRK, RK, LASIK, LASEK, or another type of refractive procedure, and cataract surgery;
  - patients requiring canthotomy to generate a flap in the non-dominant eye;
  - patients with an average corneal power of less than 41.00 D or greater than 47.00 D in the non-dominant eye;
  - patients who have a difference of 1.00 D or more between manifest and cycloplegic refraction;
  - patients with ocular hypertension and/or glaucoma suspect;
  - patients taking amiodarone hydrochloride;
  - patients taking sumatriptan;
  - patients who have a family history or signs of keratoconus, pellucid marginal degeneration, or any other condition that may cause thinning of the cornea;
  - patients with a history of eye injury;
  - patients with a past history of ocular infection or inflammation;
  - patients not within the age group specified in the indications for use.

#### POTENTIAL RISKS

The following are potential risks associated with the Raindrop Near Vision Inlay:

- Vision and Ocular Symptoms: Raindrop Near Vision Inlay implantation may cause or worsen problems with glare, halos, foreign body sensation, and pain. Some of these symptoms may be improved with additional treatment including artificial tears and punctal plugs. However, these symptoms may not resolve, even with treatment.
- Contrast Sensitivity: Raindrop Near Vision Inlay implantation may cause decreased contrast sensitivity most noticeable in the inlay implanted eye and under certain lighting conditions, like when driving at night or in very bright light. There could be a further reduction in contrast if the inlay implanted eye were to develop corneal haze and/or either eye were to develop a cataract, glaucoma, macular degeneration, or were to be implanted with a multifocal intraocular lens.
- Eye Infections: There is a risk of infection and/or inflammation to the anterior segment of the eye as a result of Raindrop Near Vision Inlay implantation.
- Dry Eyes: There is a risk of developing a new dry eye condition or exacerbation of an existing dry eye condition after the implantation procedure. A patient experiencing dry eye symptoms may require treatment with artificial tears, punctal plugs, and/or other therapy depending on the severity of the dry eye condition.
- Corneal Complications: Risk of complications to the cornea include, but are not limited to:
  - corneal haze
    - in low light conditions greater losses of contrast sensitivity may be experienced
    - best-corrected distance visual acuity may decrease
    - additional steroid therapy may be needed to treat this condition, which may result in an increase in intraocular pressure and faster cataract development than with normal aging
  - corneal ectasia
    - in a severe case, a corneal transplant might be necessary
  - scarring
  - epithelial ingrowth requiring a second surgery for removal
  - inlay extrusion, inlay shifts in position, or misaligned flap
  - epithelial defects or recurrent corneal erosion
  - inflammation, such as diffuse lamellar keratitis (DLK)
  - corneal melting or corneal swelling resulting in corneal decompensation that can cause loss of vision and may require transplant of healthy tissue from a donor
- Cataract Formation: There is a risk of developing a cataract in the implanted eye as a result of normal aging, which could impact vision in the eye sooner, and to a greater degree, with the inlay present.
- Refractive Error Change: When the Raindrop Near Vision Inlay creates a smooth gradient of power, it is inducing a zone of increased negative spherical aberration in the center of the eye which could have the potential for a decrease in uncorrected distance vision. In some cases, removal of the inlay will improve the patient’s vision but may take many months. In other cases, removal of the inlay will not improve his or her vision and the decreased vision could become permanent.
- Intraocular Pressure: There is a potential risk for intraocular pressure to increase as a result of using ophthalmic medication drops needed to suppress inflammation from inlay implantation following the surgery.
- Secondary Surgical Intervention: After Raindrop Near Vision Inlay implantation, a second surgical intervention may be needed to either remove the inlay permanently or to exchange the inlay, primarily due to misalignment over the light-constricted pupil. Other types of surgery may also be needed to treat complications, such as lifting the corneal flap under which the inlay is implanted. Each of these additional surgeries has its own risks, and may or may not completely resolve the problem.
- Posterior Segment Complications: There is a potential risk for a retinal detachment or posterior segment vascular event due to the implantation of the Raindrop Near Vision Inlay.
- Vision Loss: There is a potential risk for losing best-corrected distance visual acuity after the surgery. In some cases, removal of the inlay will improve the best-corrected distance vision but may take many months. In other cases, removal of the inlay will not improve the vision and the decreased vision could become permanent.
- Managing Eye Problems: Cataract surgery may be possible with the inlay in place. However, you may choose

to remove the inlay before such surgery. The presence of the inlay may affect eye pressure measurements, making it difficult to detect changes in eye pressure compared to before surgery. Even though the inlay is transparent, viewing, imaging, and treating other eye conditions or structures may be difficult due to the presence of the inlay.

#### DIRECTIONS FOR USE

- Two (2) days prior to surgery patient should administer one (1) drop of difluprednate 0.05% (or equivalent) four (4) times a day.
- Administer topical analgesic and appropriate concomitant medications to the patient's non-dominant eye.
- Prepare and drape the patient according to standard surgical technique.
- Place lid speculum (aspirating style is preferred, but not required) into position.
- Create corneal flap using a femtosecond laser keratome with a flap diameter of 8.0 mm or greater, and targeting 30% of the central corneal thickness. The corneal flap must be a minimum of 150 µm thick, and the residual stromal bed must be a minimum of 300 µm thick. Follow the laser keratome manufacturer’s instructions when creating a corneal flap.
- Using chilled BSS sterile irrigating solution, irrigate the cornea and remove excess fluid using an eye spear sponge from the canthus region if needed.
- If the corneal flap is irregular in size or shape, or if any complication should occur during the creation or manipulation of the flap, **DO NOT IMPLANT** the Raindrop Near Vision Inlay.
  - The surgical assistant should prepare the Raindrop Near Vision Inlay for implantation as follows using sterile, powder-free nitrile gloves.
  - Open the plastic cup containing the Raindrop Near Vision Inlay. Remove the inner cup, and identification labels from the outer plastic cup. Remove the seal of the inner cup and transfer the glass vial containing the inlay onto a sterile field.
  - Assemble sterile syringe and cannula. Hold the cannula package so the heat seal is facing away from you. Gently snap the heat seal by applying pressure with both thumbs on the package in a direction away from you. Partially remove the syringe from blister pack exposing the syringe luer fitting. While being careful not to directly come into contact with the syringe, remove the non-sterile cannula cover exposing the sterile cannula hub. Twist the cannula hub onto the end of the syringe luer until tightly connected. Remove the cover from cannula exposing the sterile cannula (**Figure 2**). Place the sterile syringe cannula assembly onto the sterile field.
  - Snap off the plastic cover from the glass vial. Carefully pull the tab off the aluminum cap and peel away from vial. Remove the rubber stopper. Carefully remove the Inlay Inserter from the glass vial using forceps. Do not touch the inserter cap on sides of the vial.
  - Attach the shaft of the Inlay Inserter to the round open end of the Inlay Inserter Chuck Handle. Refer to the Inlay Inserter Chuck Handle Instructions for Use (310-0007) for detailed instructions on preparing and assembling the Inlay Inserter Chuck Handle and attaching the Chuck Handle to the Inlay Inserter (**Figure 3**).
  - Hold the Inlay Inserter Chuck Handle so that the inserter cap is facing upward and carefully slide the tip of cannula needle through the hole in the cap until it seats on the tip of Inlay Inserter (**Figure 4a**). Using your thumb, retract the plunger of the syringe about 1.5 cc (approximately 1/2 inch) (**Figure 4b**) and then vertically withdraw the cannula-syringe assembly while maintaining alignment with the center axis of the hole in the cap (**Figure 4c**).
  - While maintaining the cap in the upward facing direction, firmly grasp the main body of the cap using forceps and pull the cap vertically to remove the cap from the Inlay Inserter (**Figure 5**).
  - The Raindrop Near Vision Inlay is now ready for surgical delivery. Verify the Raindrop Near Vision Inlay is in position by locating the edge within the Inlay Inserter slot (**Figure 6**). The Raindrop Near Vision Inlay should be delivered immediately to avoid dehydration.
- Align patient in proper position with the operative eye centered under the microscope and fixated on the light. Increase light brightness so that the pupil is approximately 3.0 mm or smaller in diameter.
- Position the tip of the Inlay Inserter above the stromal bed and centered over the light-constricted pupil. Gently lower the Inlay Inserter on to the stromal bed and transfer the Raindrop Near Vision Inlay from the Inlay Inserter to the stromal surface using a disposable 30 gauge cannula or spatula and pull the Inlay Inserter away from the Raindrop Near Vision Inlay.
- Utilizing the elbow of the cannula or spatula, manipulate the Raindrop Near Vision Inlay into position

centered on the light-constricted pupil. The microscope reticule mires will aid in ensuring its proper positioning on the light-constricted pupil.

12.Visually inspect the Raindrop Near Vision Inlay for damage.

13.Allow the Raindrop Near Vision Inlay to adhere to the stromal bed by letting it rest for approximately one (1) minute without manipulation.

14.Reposition the flap by placing a small amount of **BSS ONLY** at the hinge and stromal surface of the flap. Avoid any irrigation under the flap, as this may cause the Raindrop Near Vision Inlay to become misaligned, damaged or lost.

**WARNING:** Do not expose the corneal stromal interface to medications or lubricants. These should be administered only after confirming that no further surgical manipulation is required, which is determined by verifying at the slit lamp the centration of the Raindrop Near Vision Inlay and the proper position of the LASIK flap (see centration instructions below). Exposure of medications or lubricants to the stromal interface may induce DLK and/or flap slippage. Balanced salt solution (BSS) is the only fluid that should contact the stromal interface.

#### POSTOPERATIVE CARE FOLLOWING INLAY IMPLANTATION

- Check the eye at a slit lamp to ensure that the Raindrop Near Vision Inlay is centered over the light-constricted pupil, and that the flap is properly repositioned. The microscope reticule mires will aid in the observation and assessment of the Raindrop Near Vision Inlay centration.
  - Methodology for assessing centration of the inlay at slit lamp. Conduct the slit lamp examination by retroillumination; to assess centration of the Raindrop Near Vision Inlay, ask the patient to look straight at the light while covering the dominant eye. Once the Raindrop Near Vision Inlay is located, direct the beam of light to the side of the Raindrop Near Vision Inlay to assess its centration in relationship with the center of the light-constricted pupil.
  - If the corneal flap is not properly positioned, re-lift the flap carefully using forceps, hydrate it with **BSS ONLY** and close it again, making sure it is centered and smooth. If flap remains misaligned, then discomfort, epithelial ingrowth, flap wrinkling, or dislodgement may occur.<sup>3</sup>
  - If the Raindrop Near Vision Inlay appears to be misaligned, if necessary, lift the flap and recenter the Raindrop Near Vision Inlay using a drop of sterile **BSS ONLY**. Let the Raindrop Near Vision Inlay dry completely before closing the flap. Verify centration as described above.
- If centration is adequate and the flap is properly repositioned, administer postoperative benzalkonium chloride-free drops, including a strong steroid and antibiotic.
- Instruct the patient on the proper use and duration of postoperative medications.
  - Use topical ophthalmic antibiotic, such as moxifloxacin hydrochloride ophthalmic solution 0.5% (or equivalent), four (4) times a day for a minimum of one (1) week;
  - Use ophthalmic steroid suspension, such as difluprednate 0.05% (or equivalent), tapered for a month (four [4] times a day for the first week; three [3] times a day for the second week; two [2] times a day for the third week; and one [1] time a day for the fourth week);
  - Switch to a weaker ophthalmic steroid, such as loteprednol etabonate ophthalmic 0.5% (or equivalent), tapered for two (2) months (two [2] times a day for the second month, then one [1] drop a day for the third month postoperatively).
- Shield the eye prior to discharging the patient. Instruct the patient to continue to wear the protective shield during sleep for up to four (4) weeks and avoid eye rubbing.
- If by the one week postoperative visit, the Raindrop Near Vision Inlay appears to be misaligned and the near vision has not improved from preoperative levels repeat step 1.3 in this section.

Frequent postoperative follow-up examinations must be performed for at least the first year following implantation to look for postoperative complications and adverse events. We recommend the following postoperative follow-up schedule, at minimum, during the first year following implantation of the inlay: 1 day, 1 week, 1 month, 6 months, and 12 months. An eye care professional must monitor the patient’s vision, refraction, and ocular health regularly thereafter, as long as the inlay is implanted.

**SURGICAL PROCEDURE FOR INLAY REMOVAL**

The following is the recommended procedure for removal of the inlay:

- prepare the eye as per sterile technique with anesthetic;
- locate the flap side cut, and open the flap using a femtosecond laser incision opening spatula or forceps;
- locate the inlay (it could be on the stromal bed or on the undersurface of the flap);
- using a spatula, gently remove the inlay from the stroma;
- irrigate the stromal bed with **BSS ONLY**;
- replace the flap with proper alignment;
- perform postoperative evaluation of the cornea verifying safe removal and proper flap positioning.

**POSTOPERATIVE CARE FOLLOWING INLAY REMOVAL**

The following are the recommended postoperative care instructions following the removal of the inlay and after the flap is properly positioned:

- a topical ophthalmic antibiotic four (4) times a day for a minimum of one (1) week;
- ophthalmic steroid, such as loteprednol etabonate 0.5% (or equivalent), four (4) times a day for the first week and taper as needed;
- monitor patient recovery with regular follow up exams. The surgeon should monitor the recovery of the patient's best-corrected visual acuity.

The patient may experience delayed recovery of best-corrected distance visual acuity following removal, and there is a potential for loss of uncorrected and best-corrected visual acuity. This should be described to all patients in the informed consent document.

**REFERENCES**

1. Data on File at ReVision Optics, Inc.
2. Pinsky, P. Three-Dimensional Modeling of Metabolic Species Transport in the Cornea with a Hydrogel Intrastromal Inlay. *Invest Ophthalmol Vis Sci.* 2014;55:3093-3106.
3. Lam D, Leung ATS, et al. Management of severe flap wrinkling or dislodgement after laser in situ keratomileusis. *J Cataract Refract Surg.* 1999;25:1441-1447.

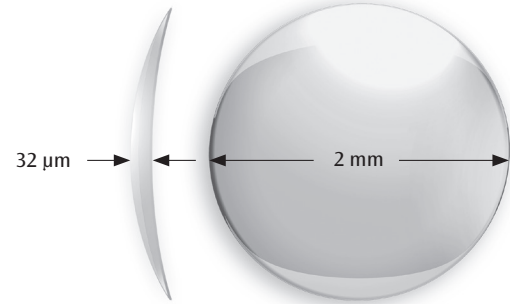
**SYMBOLS ON PACKAGING**

SYMBOLS	EXPLANATION (English)
	Manufacturer
	Lot Number
	Use-by date (YYYY-MM-DD: Year-Month-Day)
	Catalog Number
	Consult instructions for use
	Serial Number
	Sterilized using steam
	<b>CAUTION:</b> Federal law restricts this device to sale by or on the order of a physician.
	Diameter
	Do not re-use
	Do not use if package is damaged
	Temperature Limit 5°C (41°F) - 55°C (131°F) Max.
	Do not re-sterilize
	Caution (consult instructions for use)

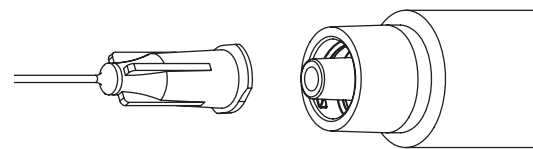
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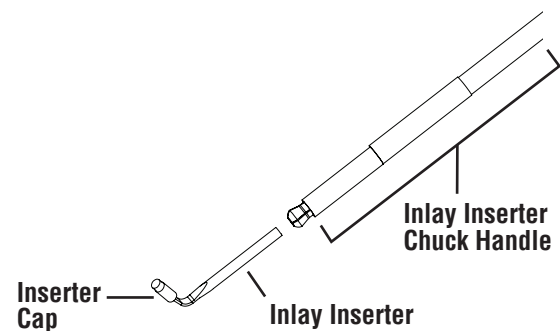
**Figure 1 The Raindrop Near Vision Inlay**



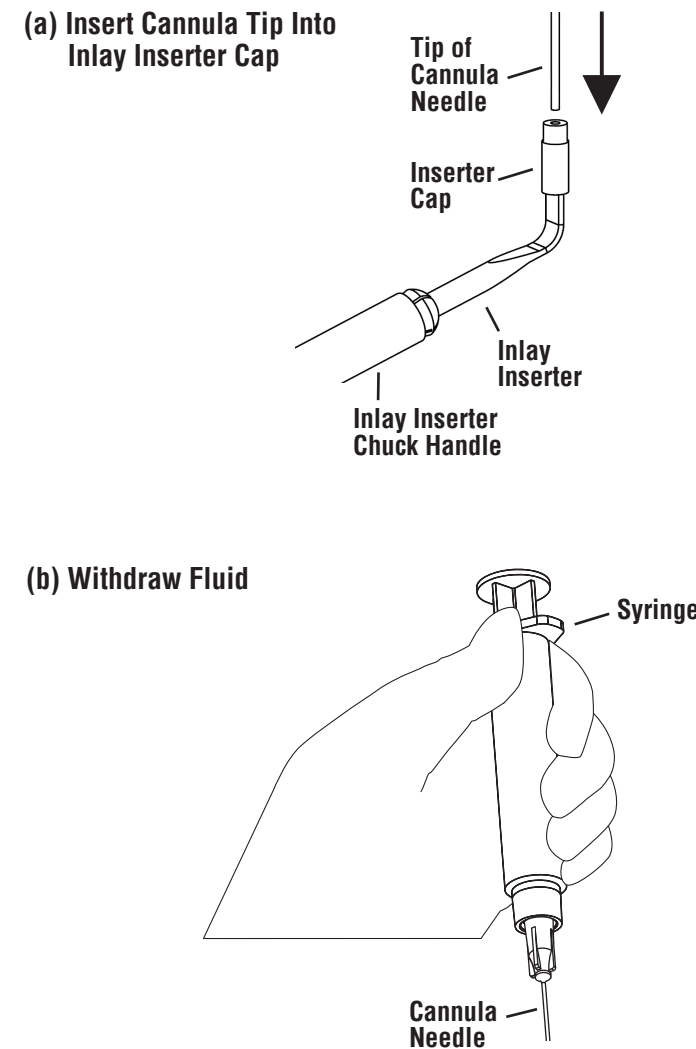
**Figure 2 Cannula And Connection Hub Of Syringe**



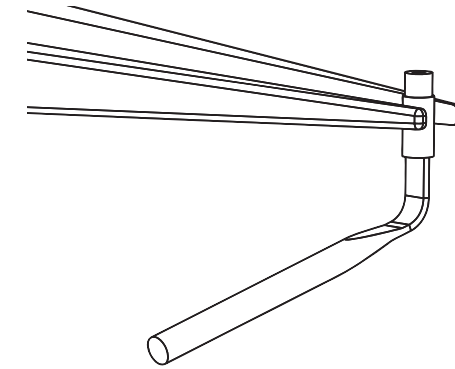
**Figure 3 Orientation Of Chuck Handle And Inlay Inserter For Attachment**



**Figure 4 Removing Fluid From The Inserter Cap**



**Figure 5 Removing Cap From Inlay Inserter**



**Figure 6 Raindrop Near Vision Inlay In The Inlay Inserter**

