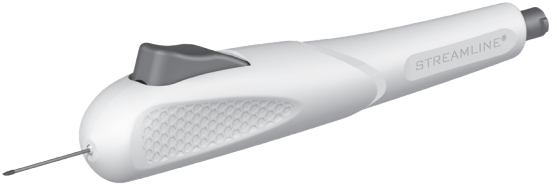
STREAMLINE®
SURGICAL SYSTEM

Instructions For Use

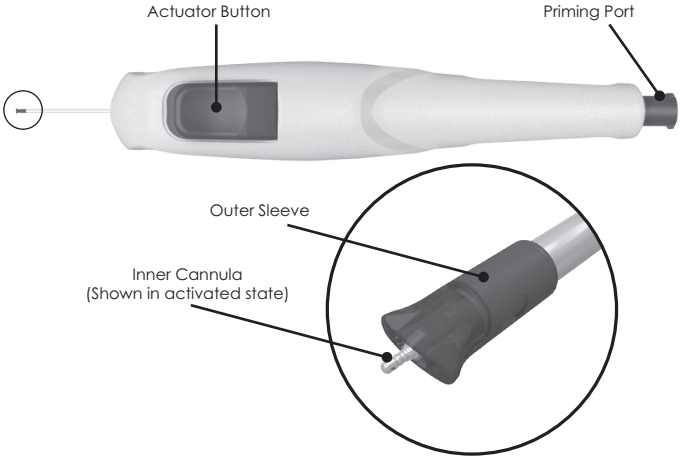
℞only **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician. Physician training (reading the Instructions for Use) is required prior to the use of Streamline®.



DESCRIPTION
The disposable Streamline® Surgical System (Streamline®) consists of a surgical grade stainless steel inner cannula with a retractable medical grade outer sleeve and body that houses a pump for the delivery of ophthalmic viscoelastic fluid. The inner cannula and outer sleeve are comprised of a long thin neck that allows access through a clear corneal incision. As the actuator button is depressed, the pump delivers a small amount of ophthalmic viscoelastic fluid. The product is designed to provide a maximum of 8 total deliveries of ophthalmic viscoelastic.

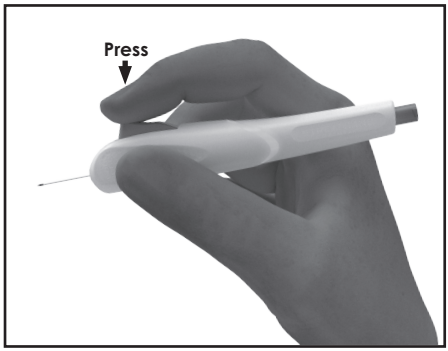
INDICATIONS FOR USE
Streamline® Surgical System is a single-use disposable cannula for use during ophthalmic surgical procedures to deliver small amounts of ophthalmic viscoelastic fluid.

The inner cutting cannula of the Streamline® Surgical System is intended to create incisions in the trabecular meshwork tissue.[1]



[1] - Class I 510(k) exempt device function

Figure A:
Proper Hand and Finger Position



CONTRAINDICATIONS
Procedures, done with Streamline®, require proper visualization. Do not attempt to use Streamline® if corneal clarity is poor or if visualization is not possible.

CAUTION: Physician training is strongly recommended to ensure proper use of this device and proper visualization. Do not use Streamline® if you are not trained or have poor visualization. Improper visualization may result in misuse of Streamline® and damage to eye structures.

WARNINGS

A. Streamline® is a single patient, single use disposable device. Do not reuse or re-sterilize. Re-sterilized or reused devices pose risks of infection and device malfunction.

B. Do not use Streamline® if you are not trained or have poor visualization. Improper visualization may result in misuse of Streamline® and damage to eye structures.

C. Do not use Streamline® past the indicated expiration date.

CAUTIONS

A. If these instructions are not followed, OVD may not be delivered as intended.

B. Federal (USA) law restricts this device to sale, distribution, or use by or on the order of a physician. Physician training (reading these Instructions for Use) is required prior to the use of Streamline®.

C. Additional physician training is strongly recommended. Contact a New World Medical, Inc. representative for approved training options.

D. Ensure that the outer sleeve does not come in contact with anything prior to insertion into the corneal incision as this may cause damage to the inner cannula of Streamline®.

E. Streamline® is not intended to create corneal incisions.

F. Precautions standard to ophthalmic surgery should be observed when using Streamline®, including customary aseptic technique.

G. The device contains stainless steel. Some individuals may be sensitized or allergic to metals. Avoid using Streamline® in such cases.

H. Contents are guaranteed sterile provided that the package, including the tray seal, is not punctured or damaged. Do not use if the device packaging is damaged or open, or if the seal appears damaged.

I. When removing the device from its tray, ensure that the outer sleeve does not touch any part of the tray. The outer sleeve may bend if it touches the tray surface. Do not touch the outer sleeve to any surfaces other than the intended eye anatomy as it may damage the inner cannula.

J. Do not use the device if it contains debris, is bent, rusted or otherwise damaged.

K. Do not press the actuator button during removal from the packaging or before priming.

L. Use only OVD types recommended by New World Medical, Inc. with this device.

M. The fully primed volume of OVD in Streamline® allows for 8 total deliveries of OVD. The button will continue to actuate after 8 total deliveries but will not deliver OVD.

N. While priming the device, ensure that injection of OVD into the device is done slowly. If OVD is not observed exiting the outer sleeve, then the device should be discarded and replaced with another device. The device may no longer be primed once the button is first actuated.

O. Be careful to avoid touching the corneal endothelium and iris with Streamline® as you are advancing or retracting the device in the anterior chamber. When inserting the outer sleeve, ensure that the width of the outer sleeve is parallel to the corneal incision upon inserting it into the anterior chamber.

P. Used sharps are contaminated and can transmit diseases. Dispose of the device in an appropriately labeled puncture resistant biohazard sharps container immediately after use.

Q. Do not expose to direct sunlight and water.

R. Do not use Streamline® past the indicated expiration date.

INSTRUCTIONS

1. Removing the device from the plastic tray

1.1. Verify that the expiration date has not passed.

1.2. Open the box, remove and inspect the contents for damage.

CAUTION: Contents are guaranteed sterile provided that the package, including the tray seal, is not punctured or damaged. Do not use if the device packaging is damaged or open, or if the seal appears damaged.

1.3. Peel away the sealed Tyvek lid from the plastic container. Within the main tray, is a retainer tray protecting Streamline®. The surgeon or surgeon's designate can remove the retainer tray containing Streamline® and place it on the sterile field.

CAUTION: When removing the device from its tray, ensure that the outer sleeve does not touch any part of the tray. The outer sleeve may bend if it touches the tray surface. Do not touch the outer sleeve to any surfaces other than the intended eye anatomy as it may damage the inner cannula.

CAUTION: Do not press the actuator button during removal from the packaging or before priming.

1.4. Inspect the device for debris, damage or rust.

CAUTION: Do not use the device if it contains debris, is bent, rusted or otherwise damaged.

2. Considerations

2.1. Procedures, done with Streamline®, require proper visualization. Do not attempt to use Streamline® if corneal clarity is poor or if visualization is not possible.

2.2. Streamline® can be used stand-alone or combined with other ophthalmic surgical procedures.

2.3. The Streamline® outer sleeve is inserted into the eye through a previously created clear corneal incision. The width of the outer sleeve should be parallel to the clear corneal incision in order to enter the anterior chamber without damage to the cornea. The minimum size clear corneal incision that allows for use of Streamline® is 1.8 mm.

CAUTION: Streamline® is not intended to create corneal incisions.

2.4. The anterior chamber should be filled with OVD to maintain stability prior to and during the use of Streamline®.

3. Using Streamline® to create incisions in the trabecular meshwork tissue[2]

3.1. With your hand stabilized, touch the outer sleeve against the trabecular meshwork to slightly applanate the tissue without pushing or indenting the eye wall. Actuate Streamline® by fully depressing the button in one smooth continuous motion, while maintaining the device position and view of anatomical structures throughout the motion. Actuation of the button retracts the outer sleeve, allowing the inner cutting cannula to incise the trabecular meshwork. While keeping the button depressed and the outer sleeve retracted, the initial incisional goniotomy can be extended to the desired length by directing the exposed cutting cannula across the canal.

4. Priming Streamline®

CAUTION: Use only the OVD types recommended by New World Medical, Inc. with this device.

4.1. To reduce the presence of air bubbles, expel air from the OVD syringe prior to connecting the luer fitting of the OVD syringe to the Streamline® priming port at the proximal end of the device and twist to lock.

[2] - Class I 510(k) exempt device function

4.2. Depress the OVD syringe plunger to dispense OVD into Streamline®. Once OVD is seen flowing out of the Streamline outer sleeve without any bubbles, the device is fully primed and air should be flushed from the device.

4.3. Remove the OVD syringe from the Streamline® priming port by twisting to unlock before next steps.

CAUTION: While priming the device, ensure that injection of OVD into the device is done slowly. If OVD is not observed exiting the outer sleeve, then the device should be discarded and replaced with another device.

5. Using Streamline® to deliver OVD

5.1. See figure A for proper hand and finger position while handling the Streamline® device.

5.2. Insert the outer sleeve of Streamline® into the anterior chamber through an existing clear corneal incision (minimum 1.8 mm in size). Advance the outer sleeve past the pupil.

CAUTION: Be careful to avoid touching the corneal endothelium and iris with Streamline® as you are advancing or retracting the device in the anterior chamber. When inserting the outer sleeve, ensure that the width of the outer sleeve is parallel to the corneal incision upon inserting it into the anterior chamber.

5.3. Actuate Streamline® by fully depressing the button in one smooth continuous motion, while maintaining the device position and view of anatomical structures throughout the motion. Actuation of the button retracts the outer sleeve, and dispenses OVD. Streamline® will deliver 7µL of OVD per actuation. NOTE: It is important that the button is depressed until no further motion is possible to ensure full delivery of OVD.

5.4. With the button fully pressed, maintain position of the outer sleeve for approximately 2 seconds to fully dispense OVD.

5.5. After 2 seconds of delivery of OVD is complete, move 1-2 mm away from the treated area, and lift the finger away from the button. Lifting of the finger off the button will cause the outer sleeve to reposition over the inner cannula and prepare the device for the next delivery of OVD.

5.6. Once the desired number of deliveries are completed, the device can be removed from the anterior chamber keeping the width of the outer sleeve parallel with the corneal incision to avoid trauma to the cornea during removal.

5.7. Irrigate and aspirate any remaining OVD out of the anterior chamber, inflate the anterior chamber with balanced salt solution and hydrate the corneal wounds as per standard practice.

6. Disposal

6.1. Immediately after use, dispose of the device in an appropriately labeled puncture resistant biohazard sharps container.

CAUTION: Used sharps are contaminated and can transmit diseases. Immediately after use, dispose of the device in an appropriately labeled puncture resistant biohazard sharps container.

WARNING: Streamline® is a single patient, single use disposable device. Do not reuse or re-sterilize. Re-sterilized or reused devices pose risks of infection and device malfunction.

HOW SUPPLIED
One Streamline® is supplied per box. Streamline® is packaged in a plastic tray with a Tyvek lid. The tray secures and protects the device. Streamline® is a disposable, single patient, single use, sterile surgical device.

Streamline® is sterilized with gamma irradiation.

STERILE R

STORAGE REQUIREMENTS
Streamline® should be stored at room temperature.

CAUTION: Do not expose to direct sunlight and water.

EXPIRATION DATE
Streamline® can be used after the date of manufacture until the expiration date as indicated on the label. Sterility is guaranteed until the expiration date if the packaging is not punctured or otherwise damaged.

CAUTION: Do not use Streamline® past the indicated expiration date.

RECOMMENDED OPHTHALMIC VISCOSURGICAL DEVICES (OVD)
The OVD's qualified for use with the Streamline® are:

OVD	Classification	Manufacturer
Viscoat®	Dispersive	Alcon
DisCoVisc®	Dispersive/Cohesive	Alcon
Amvisc® Plus	Dispersive/Cohesive	Bausch + Lomb
ProVisc®	Cohesive	Alcon
Amvisc®	Cohesive	Bausch + Lomb
Healon® Pro	Cohesive	Johnson & Johnson
Healon® GV Pro	Cohesive	Johnson & Johnson

CAUTION: Use only OVD types recommended by New World Medical, Inc. with this device.

POTENTIAL ADVERSE EVENTS
Adverse events that may be reasonably associated with the use of Streamline® in the eye include but are not limited to the following: elevation of intraocular pressure, anterior chamber shallowing, Descemet's membrane tear or detachment, intracorneal hematoma, corneal decompensation, corneal injury, corneal edema or opacification, cyclodialysis cleft, hyphema, hypotony, hypotony maculopathy, IOL dislocation, cataract formation, iris injury, iris tear, iridodialysis, change to pupil shape, loss of vitreous, perforation of sclera, choroidal effusion, suprachoroidal hemorrhage, vitreous hemorrhage, retinal detachment, retinal dialysis, retinal tear, endophthalmitis or other ocular infection.

ADVERSE EVENT REPORTING
Adverse events and/or potentially sight-threatening complications that are reasonably associated with the use of Streamline® must be reported to New World Medical, Inc.

USE OF SYMBOLS
The following symbols used in the Streamline® packaging are defined below.

	English
	Manufacturer
	Date of Manufacture YYYY-MM
	"Use-by" or Expiration date
	Lot Number
	Model/Catalogue Number
	Serial Number
	Sterilized using irradiation
	Do not use if package is damaged
	Do not resterilize
	Do not re-use
	Consult Instructions for Use
	Caution
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Physician training (reading the Instructions for Use) is required prior to use of Streamline®.
	Keep away from sunlight
	Peel Direction

NEW WORLD
MEDICAL

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50-0145 REV D. 2022-11