

**PACKAGE INSERT  
STAAR SURGICAL COMPANY  
AQUAFLOW™ COLLAGEN GLAUCOMA DRAINAGE DEVICE,  
MODEL CGDD-20**

**DEVICE DESCRIPTION**

The STAAR AquaFlow™ Collagen Glaucoma Drainage Device is designed to maintain a sub-scleral space following non-penetrating deep sclerectomy following non-penetrating deep sclerectomy. After placement in the sub-scleral space and exposure to ocular fluids, the device swells as it absorbs aqueous. Subsequently, the device begins to slowly dissolve until it is completely resorbed within 6-9 months. The AquaFlow™ is sterilized using gamma radiation. The AquaFlow device has a cylindrical shape; it is 4.0 mm long by 0.5 mm wide (when dry) and is composed entirely of lyophilized, cross-linked porcine collagen. Tensile strength is  $25 \times 10^5 \text{ N/m}^2$ , specific gravity (when hydrated) is 1.001 g/cm<sup>3</sup>.

**INDICATIONS**

The AquaFlow™ is indicated for the maintenance of a sub-scleral space following non-penetrating deep sclerectomy used to facilitate aqueous outflow for the reduction of intraocular pressure in patients with open angle glaucoma where intraocular pressure remains uncontrolled while on maximally tolerated medical therapy.

**CONTRAINDICATIONS**

The AquaFlow™ is contraindicated under the following circumstances or conditions:

1. Known allergic reaction to porcine-derived products.
2. Known allergic reaction to collagen
3. In eye(s) with angle closure glaucoma

**PRECAUTIONS**

1. The effectiveness of the AquaFlow™ device has not been established in patients with pseudophakic, secondary, uveitic or neovascular glaucoma or discernible congenital anomalies of the anterior chamber angle.
2. The use of the AquaFlow™ device has not been studied as an alternative to the primary treatment of glaucomatous symptoms with medications. The

effectiveness of this device has been demonstrated only in patients with uncontrolled intraocular pressure who were receiving maximally tolerated glaucoma medications and who underwent successful non-penetrating deep sclerectomy. The device has not been studied as an alternative to trabeculectomy or non-penetrating deep sclerectomy without use of an AquaFlow™ device.

3. The safety and effectiveness of the AquaFlow™ as a secondary device in eyes that have previously undergone non-penetrating deep sclerectomy with implantation of an AquaFlow™ device has not been established.
4. The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. If intraocular pressure is not adequately maintained after surgery, the surgeon should consider an appropriate medication regimen to reduce intraocular pressure or a goniotomy to re-establish communication of aqueous between the anterior chamber and the scleral drainage site.
5. Dosage regimens for administration of postoperative steroids in conjunction with the AquaFlow™ and non-penetrating deep sclerectomy procedure were not examined in the clinical study. If steroids are administered postoperatively, it is recommended that the surgeon be alert to potential sequelae to those medications.
6. The device should be carefully examined in the operating room for breaks and proper sizing prior to placement. The device should not be exposed to any solutions prior to placement in the operating field.

## ADVERSE EVENTS

A summary of adverse events reported in the 194 eyes enrolled during the clinical trial (at any postoperative exam) is presented below:

<u>Adverse Event</u>	<u>N</u>	<u>%</u>
Endophthalmitis	0	-0-
Central retinal artery occlusion*	1	0.5
Secondary Surgical Intervention Required		
for cataract surgery	16	8.2
for wound leak repair	5	2.6
for secondary filtering procedures	3	1.5
for lysis of bleb adhesions	2	1.0
for wound revision due to iris prolapse	1	0.5
for iris sweep	1	0.5
for superficial keratectomy	1	1.0
for removal of device	0	-0-

Other potentially sight-threatening complications reported during the clinical study were:

<u>Complication</u>	<u>Cumulative</u>		<u>Reported After 1 Week Postoperative</u>	
	<u>N</u>	<u>%</u>	<u>N</u>	<u>%</u>
Hypotony (IOP < 5 mm Hg)*	62	31.9	8	4.1
Cataract Progression	40	20.6	n/a	n/a
Shallow Anterior Chamber*	22	11.3	7	3.6
Choroidal Detachment/Effusion*	8	4.1	5	2.6
Flat Anterior Chamber*	1	0.5	0	-0-
Iris Prolapse to Sclerectomy Site*	1	0.5	n/a	n/a
Cataract Formation	0	-0-	0	-0-
Hypotony maculopathy	0	-0-	0	-0-

\*None of these complications were persistent; all had resolved at 6 months postoperative.

## **CLINICAL TRIAL**

### **Summary Findings of the Clinical Studies:**

The Model CGDD-20 was found to be safe and effective at maintaining a sub-scleral space following non-penetrating deep sclerectomy used to facilitate aqueous outflow for the reduction of intraocular pressure in patients who had open angle glaucoma where intraocular pressure remained uncontrolled while on maximally tolerated medical therapy.

## Description of the Clinical Trial

The clinical trial of the AquaFlow™ Collagen Glaucoma Drainage Device began on January 8, 1998. The study was designed to determine the safety and effectiveness of the device in the reduction of intraocular pressure in patients with open angle glaucoma who were on maximally tolerated medications. 194 eyes involving 130 patients were enrolled under a single study phase in a non-randomized fashion at nine geographically distributed sites and their results were compared to literature controls. Criteria for inclusion in the study were: male or female phakic patients of any race between 35 and 85 years of age at the time of surgery with one of following types of glaucoma in the study eye: primary open-angle glaucoma eye or open-angle glaucoma 4 weeks or more after a laser iridotomy, provided the eye was not inflamed and steroids had not been used for one week before surgery and less than 1/12<sup>th</sup> of the trabecular meshwork circumference was blocked by peripheral anterior synechiae. The study eye had to be on maximal tolerated medical therapy with an intraocular pressure (IOP)  $\geq$  18 mm Hg.

As of the date of database cut-off, May 25, 2000, 183 cases had complete data reports at 6 months of postoperative follow-up and 138 had complete reports at 12 months of follow-up. The remaining 56 cases were not yet eligible for 12 month follow-up at the time of closure of the database. Results from this study for postoperative follow-up longer than 12 months have not yet been established.

This study population consisted primarily of elderly, Caucasian patients on whom fornix-based conjunctival flaps were made. The effect of preoperative demographic factors on postoperative outcomes was examined. Change in intraocular pressure from baseline (preoperative) was examined. No statistically significant postoperative effects due to patient race were found. There was insufficient information to further study the effect of race. Patient age did significantly affect surgical outcomes. Increases in patient age were associated with decreased postoperative intraocular pressure with patients over age 60 more likely to achieve "overall success".

**Case Population**  
**Baseline (Preoperative) Demographic Characteristics of Study Cases**  
**N = 194**

Sex:	Male	54 (41.5%)
	Female	76 (58.5%)
Race:	Caucasian	103 (79.2%)
	Black	16 (12.3%)
	Other Races	11 (8.5%)
Conjunctival Flap:	Fornix-based	178 (91.8%)
	Limbal-based	16 (8.2%)
Mean Age:		66.7 years
Type of Glaucoma:	Primary Open Angle	188 (96.9%)
	Pigmentary	3 (1.5%)
	Pseudoexfoliation	2 (1.0%)
	Other	1 (0.5%)

Mean Intraocular Pressure (mm Hg)							
Postoperative Examination Interval							
	Preoperative	< 1 week	1-3 Weeks	1-2 Months	2-3 Months	4-7 Months	1 Year*
Mean	24.2	7.6	13.67	16.7	16.1	16.3	16.5
Std. Dev.	5.64	5.27	6.03	4.86	4.3	5.4	4.2
Minimum	18.0	0	2.0	6.0	4	6.0	8
Maximum	56.0	34.0	33.0	36.0	29	62.0	42.0
Total Cases Reported	194	193	183	184	179	182	138

\*Excludes three patients who underwent additional filtering surgery prior to one year postoperative

Surgical Outcomes At 12 Months Postoperative - PMA Cohort (N=141)		
Complete Success (IOP ≤ 21 mm Hg, No IOP Medications Required)	102/141	72.3%
Overall Success (IOP ≤ 21 mm Hg, with or without IOP Medications Required)	127/141	90.1%
Failure (IOP > 21 mm Hg, with or without IOP medications)	14/141	9.9%

## **DIRECTIONS FOR USE**

The collagen device is intended for placement only after successful non-penetrating deep sclerectomy has been performed. As with many new procedures, there is a significant learning curve associated with this procedure and outcomes might be affected by the surgeon's level of experience. It is recommended that the surgeon be experienced in the non-penetrating deep sclerectomy procedure prior to using the AquaFlow™ device.

If significant perforation into the anterior chamber occurs or adequate and continuous aqueous flow at Schlemm's canal cannot be achieved, it is recommended that the surgeon switch to a standard filtration (trabeculectomy) procedure.

The surgeon should consider reviewing pertinent articles from the medical literature regarding techniques for performing the non-penetrating deep sclerectomy. Copies of selected references are available at STAAR Surgical Company and will be furnished upon request.

1. The peel pouch containing the AquaFlow™ device should be opened onto the sterile field.
2. Record the control number from the peel pouch on the operative report to maintain traceability.
3. The AquaFlow™ device should be kept dry until it is placed in the operative field.
4. Caution: Do not use the device if the package has been opened or damaged. In such cases, the sterility of the device may be compromised.

## **INSTRUCTIONS FOR USE**

After completion of a successful non-penetrating deep sclerectomy, the surgeon should place the AquaFlow™ device in the operative site and push it anteriorly until it overlays the Canal of Schlemm. A single, 10-0 nylon suture at the midpoint of the device should be used to secure it to the sclera. The device will begin to hydrate as soon as it contacts aqueous fluid. The scleral flap should then be secured over the device with a single 10-0 suture at each distal corner followed by closure of Tenon's capsule and the conjunctiva.

## **PATIENT REGISTRATION INSTRUCTIONS AND REPORTING**

### **Registration**

Each patient who receives a STAAR Surgical Company (STAAR) AquaFlow™ must be registered with STAAR at the time of device implantation.

Registration is accomplished by completing the Device Accountability Form (postcard) that is enclosed in the unit box and mailing it to STAAR Surgical Company. Patient registration is essential for STAAR Surgical Company's long-term patient follow-up program and will assist STAAR in responding to Adverse Event Reports and/or potentially sight-threatening complications.

An Implant Identification Card is supplied in the unit package. This card should be given to the patient with instructions to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

#### Reporting

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as device related and that were not previously expected in nature, severity or incidence must be reported to STAAR Surgical Company at:

National (USA) Toll Free: (800) 292-7902

OR: (626) 303-7902

FAX: (626) 303-2962

#### HOW SUPPLIED

Each AquaFlow™ device is supplied sterile and nonpyrogenic in peel-pouches. The pouches are placed in a unit box with labels and product information. The device has been sterilized with gamma radiation..

#### EXPIRATION DATE

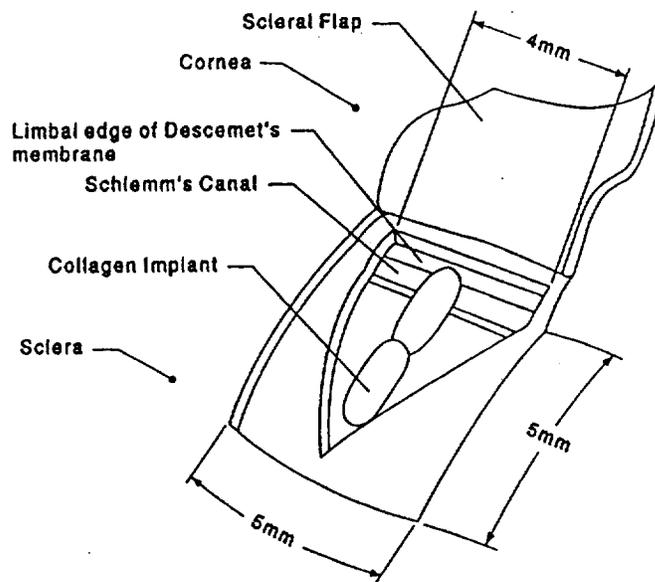
The expiration date on the device package is the sterility expiration date. In addition, there is a sterility expiration date that is clearly indicated on the outside of the unit box. Sterility is assured if the pouch seals are not punctured or damaged until the expiration date. This device should not be used past the indicated sterility expiration date.

#### RETURN GOODS POLICY

Contact STAAR Surgical Company.

#### CAUTION

Federal law restricts this device to sale by, or on the order of, a physician.



**CE 0124**

STAAR SURGICAL COMPANY OPERATES IN COMPLIANCE WITH THE  
 MEDICAL DEVICE DIRECTIVE 93/42/EEC AND (APPLICATION NORM TO EN  
 9001) AND EN46001.

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