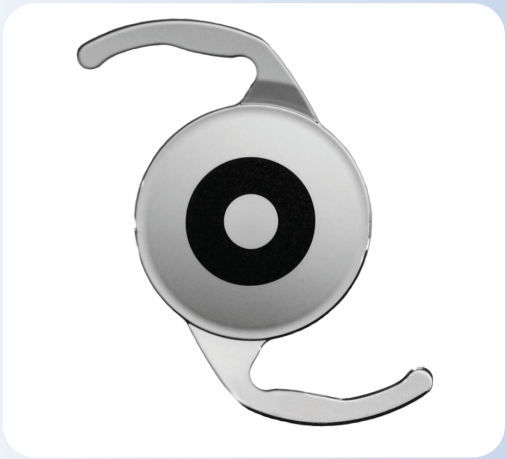
AcuFocus™
The Small Aperture Company™

IC-8™ Small Aperture IOL



CLINICAL PEARLS
QUICK REFERENCE GUIDE

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IC-8™

Small Aperture IOL

Image courtesy Professor H.B. Dick PhD, MD

METHOD OF ACTION

- The **IC-8** IOL is a single-piece, hydrophobic acrylic intraocular lens with an embedded **FilterRing™** device with a central aperture of 1.36 mm
- Using small aperture technolgy, the IOL provides a continuous depth of focus up to 3.0 D range of 20/32 vision
- Intended for implantation in the capsular bag

SPECIFICATIONS

- Diopter Range: +10.0 D to +30.0 D (0.50 diopter steps)
- IOL design: single-piece
- Edge design: 360° posterior square edge
- Material: UV blocking hydrophobic acrylic
- Optic:
  - Diameter: 6 mm
  - Shape: biconvex, anterior aspheric surface
- Overall diameter: 12.5 mm
- Haptic design: modified C with 5° angulation
- Single Use Injector System

PATIENT POPULATION

- Scheduled to undergo intraocular lens implantation in one or both eyes
- Adults
- Free from significant ocular or systemic conditions, which would impact vision or ocular health

CONTRAINDICATIONS

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected.*

- Chronic uveitis
- Age of less than 18 years
- Microphthalmia
- Corneal dystrophy or endothelial insufficiency
- Active ocular diseases (active diabetic retinopathy, uncontrolled glaucoma)

*For additional guidance refer to the **IC-8™** IOL Instructions for Use

PRE-OP TESTING

- Standard pre-op cataract patient testing
- Uncorrected and Best-corrected visual acuity
  - Distance (UCDVA, BCDVA)
  - Near (40 cm) (UCNVA, BCNVA)
- Corneal astigmatism of ≤1.50 D
- Mesopic pupil size <5.5 mm
- Biometry

BIOMETRY	
Optical Biometry IOL Parameters (partial coherence interferometry)	**Ultrasound Biometry IOL Parameters**
ACD: 6.42	ACD: 6.22
A-Constant: 120.5	A-Constant: 120.15
Surgeon Factor: 2.64	Surgeon Factor: 2.44
Manufacturer: AcuFocus, Inc. Model: **IC-8**™ IOL Type: Posterior Chamber Material: Acrylic (Optic and Haptic)	

These are all initial suggestions. The surgeon should refine A-constants based on experience, technique and outcomes. Start with one patient at a time.

SETTING PATIENT EXPECTATIONS

For maximum patient satisfaction, set appropriate expectations for a patient considering the **IC-8™** IOL.

1 Explain the Goal

- **Improve** functional near, intermediate and distance vision
- **Reduce** dependency on glasses
- Provide examples:
  – See numbers on a mobile phone
  – Send text messages
  – Read newspaper
  – Read food labels

2 May Need Magnification

- Dim light conditions
- Prolonged near vision activities
- Tiny print

3 Set Realistic Expectations

- Recovery takes time
  – Days, weeks, sometimes a little longer
- Avoid reading glasses
- Use artificial tears

PROCEDURE OVERVIEW

- Bilateral procedure per surgeon's normal standard of care
- IOL power selection based on achieving a postoperative refractive target:
  - Monofocal IOL
    - Achieve a target refraction of Plano (0.00 D)
  - **IC-8**™ IOL
    - Achieve a target refraction of -0.75 D

- Post-operative residual cylinder (>1.50 D) can be managed by incision placement and/or the use of a toric IOL for the monofocal eye only
- **IC-8** IOL corneal incision size: 3.5 mm
- Capsulorhexis: 5.0 to 5.5 mm in diameter
- Polish posterior & anterior capsule

Single Use Injector

- Injector validated viscoelastic: 1% Sodium Hyaluronate

POST-OPERATIVE CARE

Use surgeon's normal standard of care

- **IC-8™** IOL specific requirements:
  - Auto refractors and retinoscopy are unreliable or unattainable postoperatively
    - They do not work due to the small aperture opening in the **FilterRing™** device.
    - Do not use to determine the manifest refraction
  - Maximum plus refraction
    - Patients with the **IC-8** IOL may not detect small changes in power because of the small aperture
  - Use good light on reading card and for acuity testing
- Dry eye management and testing as usual for cataract

EXAMPLES OF TECHNIQUES FOR POST-OP REFRACTIONS

Due to the small aperture design, refractions can be more challenging in the implanted eye.

- The refraction end points are usually softer.
- The patient will tolerate a larger range of introduced lenses without experiencing blur.
- A "mid-point" refraction will provide the most accurate result. Alternatively, a "red/green" balance test can be used.
- NOTE: Auto refractors and retinoscopy are unreliable or unattainable postoperatively.

REFRACTION TECHNIQUE

Performing a Mid-Point Refraction

Step 1: Perform a normal manifest refraction, then instruct the patient to fixate and maintain clarity on a distance optotype 2 lines above best corrected vision.

Step 2: Add plus lenses until first blur, record their endpoint.

Step 3: Starting from the baseline manifest refraction, now add minus lenses until first blur, record endpoint.

Step 4: Calculate the mid-point refraction using the following equation:

[(Endpoint plus blur) + (Endpoint minus blur)] / 2 =
(rounded to nearest max plus 0.25 D)

Step 5: Add figure from Step 4 to the spherical component of the manifest refraction from Step 1; this represents the calculated mid-point.

Midpoint Refraction: Example

Step 1: Initial manifest Rx: +1.00 – 0.75 X 090

Step 2: Plus lenses to blur: +0.50 D (2 lenses)

Step 3: Minus lenses to blur: -1.75 D (7 lenses)

Step 4: [(+0.50 D) + (-1.75 D)] / 2 = -0.62 D (Rounded to -0.50 D)

Step 5: -0.50 D + 1.00 D = +0.50 D

Final midpoint refraction: +0.50 -0.75 X 090

REFRACTION TECHNIQUE

Alternate Refraction Method
Red/Green Balance Test

To help you find the mid-point refraction the Red/Green balance test may alternatively be utilized.

1. Complete the initial manifest refraction and dim the room illumination completely.

2. Select the projector's Red/Green filter with the appropriate target. This can be the 20/40 line or 2 lines above best corrected vision.

3. Have the patient compare the letters in the red/green sides and state which letters appear sharper, clearer or better focused or if both sides appear equally clear. (DO NOT ask if the letters are "better", "darker" or "brighter")

NOTE: If the patient is R/G colorblind this test may still be utilized because it is based on the principles of chromatic aberration and not color discrimination. The patient can still make a comparison. They should be asked to compare the "left" side with the "right" side rather than red vs. green.

- **RED IS CLEARER:**
  Place an additional 0.25 D of MINUS spherical power. Continue this until the patient reports equal clarity between sides or until the "green" side appears clearer.

- **GREEN IS CLEARER:**
  Place an additional 0.25 D of PLUS spherical power. Continue this until the patient reports equal clarity between sides or until the "red" side appears clearer.

- **MID-POINT REFRACTION:**
  The letters on both red and green sides appear equally clear. Remove the Red/Green filter and recheck BVA

LASER USE AFTER IC-8™ IOL IMPLANTATION

IMPORTANT:

Nd: YAG Capsulotomy

AcuFocus recommends an "omega" posterior capsulotomy pattern for the Nd: YAG procedure. This method creates an opening around the outside of the **FilterRing™** device from 5 to 7 o'clock leaving an inferior hinge. The stars on diagram below refer to the laser shots. The resulting tissue flap should naturally fall back out of view and remain connected to the capsular bag at the hinge. If the tissue flap does not fall back, fire the laser through the center of the FilterRing device to release the flap.

- Titrate Nd:YAG laser energy to the lowest level possible to produce a capsular opening.
- Avoid direct laser hits to the **FilterRing** device. Should contact be made with the **FilterRing** device:
  - Lens integrity is maintained.
  - No toxic chemicals are released.

LASER USE AFTER IC-8™ IOL IMPLANTATION

Retina Laser Warnings

- Extra care needed when performing any posterior segment laser treatment.
- Consult AcuFocus prior to performing retinal photodynamic therapy or any ocular laser procedure in **IC-8** IOL eye. Possible damage can occur to the IOL optics if the **FilterRing™** device is exposed to laser.

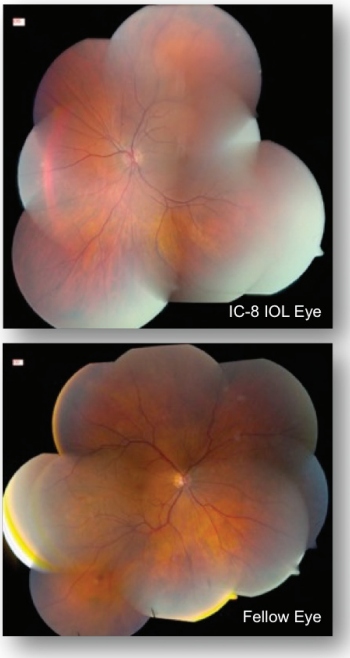

Image courtesy of Prof. Günther Grabner

If you have any questions or challenging cases, please contact your local AcuFocus representative or call Customer Service at +1 949.585.9511 Ext. 608

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