

## Device description

C-flex intraocular lenses (IOLs) are single piece ultraviolet-absorbing posterior chamber intraocular lenses for the treatment of aphakia.

C-flex IOLs are designed to be surgically implanted into the capsular bag of the human eye as a replacement for the crystalline lens following phacoemulsification, with an anterior continuous curvilinear capsulorhexis just covering 360° the anterior edge of the IOL optic by 0.5 to 1.0 mm<sup>1</sup>.

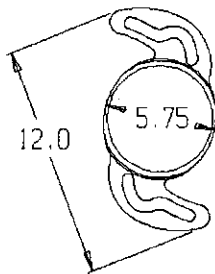
The hydrophilic nature of the Rayacryl material and the design features of the Rayner C-flex lens reduce the problems of silicone oil adhesion and silicone oil induced opacification<sup>2-5</sup>.

C-flex IOLs are available from +8.0 to +30.0 Diopters with 0.5 Diopter steps.

## IOL MATERIAL (RAYACRYL) CHARACTERISTICS

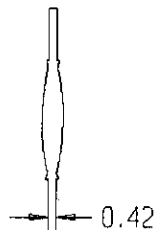
- Rayacryl (2-hydroxyethyl methacrylate/methyl methacrylate copolymer)
- Water content = 25.5% in equilibrium
- Refractive index = 1.46
- Tear strength = 3 MPa
- UV light transmission 10% cut-off = 374nm, see figure 2
- Nd:YAG laser compatible

### DIMENSIONS (figure1)



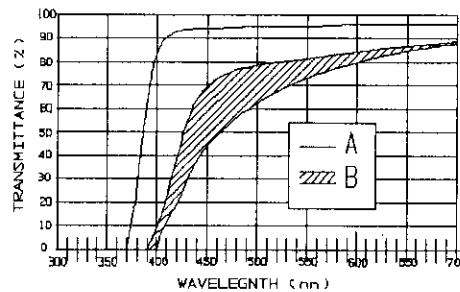
Front view of IOL

All-dimension in mm



Side view of IOL

### SPECTRAL TRANSMITTANCE (figure2)



A C-flex intraocular lens  
B Human crystalline lens aged 4 - 54 years  
(Boettner and Wolter, 1962)<sup>6</sup>

## Indications

Rayner C-flex intraocular lenses are indicated for primary implantation for the visual correction of aphakia in adults in whom a cataractous lens has been removed by phacoemulsification. The lens is intended to be placed in the capsular bag.

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### Contraindications

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

1. Microphthalmia
2. Active ocular disease (e.g. chronic severe uveitis, proliferative diabetic retinopathy, chronic glaucoma not responsive to medication)
3. Children under the age of 21 years
4. Corneal decompensation or corneal endothelial cell insufficiency
5. Persons who are pregnant or nursing

### Warnings

A risk/benefit ratio must be assessed before confirming a patient as a candidate for a C-flex IOL implantation, if they are suffering from any of the following conditions:

1. Recurrent ocular disease (e.g. uveitis, diabetic retinopathy, glaucoma, corneal decomposition)
2. Previous ocular surgery
3. Non-age related cataract
4. Vitreous loss
5. Iris atrophy
6. Severe Aniseikonia
7. Ocular Hemorrhage
8. Macular degeneration
9. Zonular dehiscence
10. Ruptured posterior capsule
11. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
12. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
13. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
14. Circumstances that would result in damage to the endothelium during implantation.
15. Suspected microbial infection.
16. Children under the age of 2 years are not suitable candidates for intraocular lenses.

Since the C-flex IOL clinical study was conducted with lens implantations into the capsular bag only, there are insufficient clinical data to demonstrate the safety and efficacy for ciliary sulcus placement.

### Precautions

1. The unopened pack must be stored in dry conditions between 0°C (32°F) and 45°C (113°F)
2. Do not use the IOL after the expiration date.
3. Check the integrity of the sterile packaging before use. Do not use if the packaging is damaged.
4. The C-flex IOL is for single use only - Do not resterilise by any method.
5. Rayner recommends using a Rayner injection system for the placement of the C-flex lens into the eye.
6. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
7. Prior to placement into the eye do not allow the IOL to contact substances that are unsterile and consequently ocular-incompatible.
8. Rayner recommends that saline must not be used as the sole lubricating agent but in combination with an ophthalmic viscoelastic device (OVD).
9. The lens must not be allowed to dehydrate. It is recommended that the lens be inserted into the eye within 3 minutes from the time of folding or loading it into an injector.
10. Non-toothed, polished instruments must be used when handling the IOL.
11. Irrigate/aspirate to eliminate any OVD residues from the bag, especially between the IOL and posterior capsule.
12. The anterior continuous curvilinear capsulorrhexis should be 360° and just cover the anterior edge of the IOL optic by 0.5 to 1.0 mm.

### Directions for use

1. Prior to implanting, examine the lens label on the unopened package for model, type, power proper configuration and expiration date.
2. To remove the lens, carefully open the peel pouch and blister tray and remove the lens in a sterile environment. When removing the lens from the blister tray, do not grasp the optical area with forceps. Prior to the actual folding or injection process, the lens should be handled by the haptic only.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
4. The lens may be soaked in sterile balanced salt solution until ready for implantation.
5. Rayner recommends that saline is not used as the sole lubricating agent, but in combination with a viscoelastic solution.
6. The lens must not be allowed to dehydrate. It is recommended that the lens be inserted into the eye within 3 minutes from the time of folding or loading it into an injector.
7. Non-toothed, polished instruments must be used when handling the IOL.
8. Rayner recommends using the Single Use Soft Tipped Disposable Injector model R-INJ-04 for the placement of the C-flex lens into the eye.

Caution: Do not use lens if the package has been damaged. The sterility of the lens may have been compromised.

### Patient registration and Reporting

A Patient Identification Card is included in the package. This is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye practitioner the patient consults in future.

Self-adhesive lens identification labels are provided for use on the Patient Identification Card and other clinical records.

Adverse events/complaints that may reasonably be regarded as lens-related and that were not previously expected in nature, severity, or degree of incidence should be reported to Rayner Intraocular Lenses Ltd. (Sackville Trading Estate, Sackville Road, Hove, East Sussex, BN3 7AN. England. UK. Tel. 01144 1273 205401, Fax 01144 1273 324623, Email: [feedback@rayner.com](mailto:feedback@rayner.com)) through your local Rayner office or distributor.

### Power calculations

The surgeon should preoperatively determine the power of the lens to be implanted. This can be calculated variously from the corneal radius, the depth of the anterior chamber and the axial length of the eye according to formulae described in the following references:

1. Retzlaff J., Sanders D. & Kraff M. Lens Implant Power Calculation, A Manual for Ophthalmologists & Biometrists - Third Edition. 1990
2. Holladay J. A Three-part System For Refining Intraocular Lens Power Calculations. J. Cataract Refract. Surg. V14:17-24, 1998
3. Holladay J. Standardizing Constants For Ultrasonic Biometry, Keratometry & IOL Power Calculations. J. Cataract Refract. Surg. V23:1356-1370, 1997
4. Hoffer K. The Hoffer Q Formula: A Comparison of Theoretic and Regression Formulas. J. Cataract Refract. Surg. V19:700-712, 1993; ERRATA, 20:677, 1994

## Clinical Studies

This C-flex intraocular lens study was a multi-center, clinical trial, with historical control designed to assess safety and efficacy.

Primary efficacy analyses are based on Best Case Visual Acuity at one year post implantation as determined in the sample of procedures with no pre-existing macular degeneration or with macular degeneration developing at any time during the study, or with a clinically significant violation of an exclusion/inclusion criteria.

Safety is evaluated with regard to specific cumulative adverse event rates and persistent adverse events rates as specified in the FDA Intraocular Lens Guidelines, 1999<sup>7</sup> and ISO 11979-7. Primary safety analyses are based on data from all enrolled procedures with follow-up to at least one-year post implantation.

The results achieved by 283 patients in the C-flex and 166 patients in the Centerflex IOLs followed for one year provide the basis for the data which were used to support that the C-flex IOL design can be used for the visual correction of aphakia.

### PATIENT POPULATION:

Three hundred and one (301) C-flex patients were enrolled (unilateral implants) in this investigation. Additionally, data from one hundred and eighty two (182) model Centerflex IOL patients was used as supporting data.

The Centerflex IOL is identical to the C-flex model in all aspects except that the C-flex additionally features an 'Enhanced Square Edge'. This feature is a 360° raised ridge encircling the periphery of both the anterior and posterior surfaces of the optic body (including the optic-haptic junction).

The patient combined C-flex/Centerflex population enrolled consisted of 63.8% females and 36.2% males. The operative eye percentage was 47.4% left and 52.6% right. Corneal status was, for the most part, normal and any pre-operative pathology was at a low percentage of the total patients enrolled. Cataract etiology was 100% senile. The mean age of males and females was 72.8 years. Ethnicity was 99.4% Caucasian, 0.4% Hispanic and 0.2% Asian.

### VISUAL ACUITY

The C-flex IOL met or exceeded historical controls for posterior chamber IOLs in all areas, for best corrected visual acuity at the 12 month post-operative examination. Best Case Visual Acuity and Overall Visual Acuity, greater than 20/40, was 98.2% and 99.5% compared to the FDA historical control figures of 92.5% and 96.7% respectively (Tables 1 & 2).

Table 1. Investigational Model vs. Historical Model  
Best Case Visual Acuity<sup>A</sup> (% with at least 20/40) One Year

Age Category	Posterior Chamber Historical Control <sup>B</sup>		Centerflex IOL		C-flex IOL		Pooled Centerflex and C-flex data	
	n/N	%	n/N	%	n/N	%	n/N	%
<60	203/206	98.5	6/6	100	24/24	100	30/30	100
60-69	793/822	96.5	41/41	100	61/61	100	102/102	100
70-79	1338/1372	97.5	71/72	98.6	116/117	99.1	187/189	98.9
≥80	601/634	94.8	17/17	100	36/36	100	53/53	100
Overall	2935/3034	96.7	135/136	99.4	237/238	99.6	372/374	99.5

Notes:

<sup>A</sup>: Best Case Visual Acuity is summarized for the Primary Efficacy Sample that excludes patients with preoperative ocular pathologies and those with macular degeneration developing at any time during the study.

<sup>B</sup>: Annex B – FDA grid of historical controls: BCVA at one year, FDA Intraocular Lens Guidelines, 1999.

Table 2. Investigational Model vs. Historical Model  
Overall Visual Acuity (% with at least 20/40) One Year

Age Category	Posterior Chamber Historical Control <sup>B</sup>		Centerflex IOL		C-flex IOL		Pooled Centerflex and C-flex data	
	n/N	%	n/N	%	n/N	%	n/N	%
<60	230/235	95.7	6/6	100	24/24	100	30/30	100
60-69	968/1012	93.4	42/42	100	66/66	100	108/108	100
70-79	1793/1920	86.5	83/84	98.8	139/140	99.3	222/224	99.1
≥80	901/1042	92.5	30/34	88.2	51/53	96.2	81/87	93.1
Overall	3893/4210	92.5	161/166	97.0	280/283	98.9	441/449	98.2

Notes:

<sup>A</sup>: Overall visual acuity is summarized for All Enrolled Procedures sample that only excludes second implants for any patient implanted bilaterally.

<sup>B</sup>: Annex B – FDA grid of historical controls: BCVA at one year, FDA Intraocular Lens Guidelines, 1999.

## SAFETY

Cumulative and persistent adverse events at one year are less than historical controls in all areas pooled except persistent macular edema, persistent corneal edema and cumulative pupillary block. The C-flex/Centerflex rates were not statistically significantly different from the grid rates for all of the listed cumulative and persistent adverse event types. Please refer to Table 3.

Table 3. Investigational Model vs. Historical Model  
Specific Cumulative and Persistent Adverse Events One Year

	Posterior Chamber Historical Control <sup>A</sup>		Centerflex IOL		C-flex IOL		Pooled Centerflex and C-flex data	
	N	%	n/N	%	n/N	%	n/N	%
Cumulative <sup>B</sup> Hyphema	91	2.2	0/182	0.0	0/301	0.0	0/483	0.0
Cumulative Macular Edema	124	2.9	5/182	2.7	6/301	2.0	11/483	2.3
Cumulative Retinal Detachment	11	0.3	0/182	0.0	0/301	0.0	0/483	0.0
Cumulative Pupillary Block	5	0.1	0/182	0.0	1/301	0.3	1/483	0.2
Cumulative Lens Dislocation	5	0.1	0/182	0.0	0/301	0.0	0/483	0.0
Cumulative Endophthalmitis	4	0.1	0/182	0.0	0/301	0.0	0/483	0.0
Cumulative Hypopyon	16	0.3	0/182	0.0	0/301	0.0	0/483	0.0
Cumulative Surgical Reintervention	46	0.8	0/182	0.0	3/301	1.0	3/483	0.6
Persistent <sup>C</sup> Macular Edema	19	0.5	3/166	1.8	2/284	0.7	5/450	1.1
Persistent Corneal Edema	11	0.3	1/166	0.6	1/284	0.4	2/450	0.4
Persistent Iritis	11	0.3	0/166	0.0	0/284	0.0	0/450	0.0
Persistent Raised IOP Requiring Treatment	17	0.4	0/166	0.0	0/284	0.0	0/450	0.0

Notes:

<sup>A</sup>: Annex B – FDA grid of historical controls: BCVA at one year, FDA Intraocular Lens Guidelines, 1999.

<sup>B</sup>: Cumulative Adverse Event (AE) for the investigational model IOL is computed as any occurrence up to and including the current interval. Historical control cumulative values are up to and including 1 year.

<sup>C</sup>: Persistent Adverse Event (AE) for the investigational model is defined as an AE remaining unresolved at the start of the current evaluation interval.

Table 3(a). Surgical Reintervention Table

Time period of occurrence	Lens	Rate of occurrence	Description and reason
1-2 days	C-flex	0.3%	"Pupillary block" due to residual viscoelastic after cataract surgery.
1-2 months	C-flex	0.3%	Reduction of visual symptoms by correcting astigmatism using "limbal relaxing incisions (LRI)".
4-6 months	C-flex	0.4%	"Refraction disorder": Post-operative corrected vision of the left eye was 20/20 and the refractive correction was as planned -2.00. However, the patient was no longer satisfied with the "monovision" status, and wanted better depth perception for a sporting activity. After many discussions with the patient, it was decided to opt for changing the refractive status of the left eye to Plano. A second implant was subsequently implanted on top of the study IOL to correct the myopia.
2 years	Center-flex	0.7%	"Corneal transplant": The patient underwent uneventful phacoemulsification and IOL implantation. The patient developed a kerato-konjunctivitis epidemica. Slit-lamp examination revealed a corneal edema and endothelitis. In the course of 18 months, corneal endothelial cell decompensation led to persisting edema followed by bullous keratopathy, corneal opacification and scarring. Corneal transplant surgery was subsequently successfully performed.

As of December 21st 2005, there were 492 implants and the overall incidence of reported adverse events is 7.11 %.

The complications experienced during the clinical trial of the C-flex and Centerflex lenses include (in order of frequency): Cumulative Macular Edema 2.3%, Persistent Macular Edema 1.1%, Vision blurred: 0.8%, Halo vision: 0.6%, Cumulative Surgical Reintervention 0.6%, Persistent Corneal Edema 0.4%, Eye pain: 0.4%, Cumulative Pupillary Block 0.2%, Fibrin deposition on the lens: 0.2%, Visual disturbance: 0.2%, Iritis: 0.2% and Cataract operation complication: 0.2%

Other potential complications of cataract or implant surgery include, but are not limited to the following: Endophthalmitis, retinal detachment, cyclitic membrane, iris prolapse, hypopyon, corneal edema, corneal endothelial damage, uveitis, hyphema, lens epithelial cell on-growth, secondary glaucoma and precipitates on the lens surface. Secondary surgical intervention may be required for, but is not limited to the following: Vitreous aspirations or iridectomy for pupillary block, wound leak repair, retinal detachment repair, lens repositioning, and lens replacement due to refractive error or severe inflammation.

#### PATIENT SATISFACTION

A modification of the patient satisfaction questionnaire used by Tester, Pace, Samore, and Olson (2000)<sup>8</sup> to assess patient reports of dysphotopsia and patient satisfaction with the investigational implant was added to the clinical follow-up assessments for patients implanted with the C-flex IOL. The design of the Centerflex study Protocol did not include these assessments.

For this questionnaire, patients are asked to rate the severity of symptoms present in their operative eye and fellow eye. Preliminary analyses revealed substantial differences in results between patients for which their fellow eye had a prior implant. These prior implants were not investigational devices and were present prior to enrollment into this study.

Satisfaction with corrected eye vision was larger for the operative eye compared to the fellow eye, a finding driven mostly by the subset of patients with no fellow eye implant. Overall satisfaction was approximately 90%. These results indicate overall patient satisfaction with the investigational device.

## Nd-YAG RATES

The neodymium:yttrium-aluminum-garnet (Nd-YAG) rates for the Centerflex and C-flex IOLs are presented in the following table.

In Rayner IOLs, ray-tracing studies show no general increase in glare as a result of the Enhanced Square Edge Technology.

Table 4.  
YAG rates

IOL model	No. of clinical sites	No. of IOLs implanted	No. of YAG procedures 12 months post-op	YAG % per overall patient no for IOL model $\leq$ 12 month post op	No. of YAG procedures 24 months post-op	YAG % per overall patient no for IOL model $\leq$ 24 month post op
Centerflex	2	182	4	2.19%	24	13.18%
C-flex	7	301	9	2.99%	16	5.31%

### How Supplied

C-flex lens is supplied in a 0.9% saline solution in a blister pack terminally sterilised with moist heat and should only be opened under aseptic conditions.

### Expiration Date

The expiration date on the lens package is the sterility expiration date. Do not use the IOL after the expiration date.

### Returns policy

Contact your local Rayner office or distributor regarding the returned goods policy. Return the lens with full identification and the reason for the return. Label the return package as a biohazard

### Bibliography

1. Schmidbauer, Josef M. M.D.; Vargas, Luis G. M.D.; Peng, Qun M.D.; Escobar-Gomez, Marcela M.D.; Werner, Liliana M.D., Ph.D.; Arthur, Stella N. M.D.; Apple, David J. M.D. International Ophthalmology Clinics. 41(3):109-131, Summer 2001.
2. Arthur S. N., Peng Q., Apple D. J., et al. Effect of heparin surface modification in reducing silicone oil adherence to various intraocular lenses. Journal of Cataract & Refractive Surgery. October 2001, Vol 27 No. 10 pp 1662-1669.
3. McLoone E., Mahon G., Archer D., Best R. Silicone oil - intraocular lens interaction: which lens to use? British Journal of Ophthalmology. May 2001, Vol 85, No.5, p543-545
4. DJ Apple, JL Federman, TJ Krolicki, et al. Irreversible silicone oil adhesion to silicone intraocular lenses. A clinicopathologic analysis. Ophthalmology, June 1996, Vol 103, 1555-1561.
5. David J Apple, MD, Robert T. Isaacs, MD, David G. Kent, FRACO, et al. Silicone oil adhesion to intraocular lenses: An experimental study comparing various biomaterials. Journal of Cataract & Refractive Surgery. May 1997, Vol 23, pp 536-544.
6. Boettner, E.A. and Wolter, J.R., "Transmission of the Ocular Media," Investigative Ophthalmology, 1:776-783, 1962.
7. FDA Intraocular Lens Guidelines, 1999.
8. Tester R, Pace NL, Samore M, Olson RJ. Dysphotopsia in phakic and pseudophakic patients: Incidence and relation to intraocular lens type. J Cataract Refract Surg. 2000 26:810-816.

### Prescription Device

FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY, OR ON THE ORDER OF A PHYSICIAN.

**C-flex**  
**ACRYLIC UV**

**THE INJECTABLE  
ACRYLIC LENS SYSTEM**

CE 0473

MM/YY

*The above is the logo and issue date to be shown on the front of the leaflet.*

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**Rayner Surgical Inc. / Designated Distributor – to be notified to FDA in due course**

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*The above address(es) and logo to be shown on the back of the instruction leaflet.*