

**Sulcoflex Duet ; An adjustable solution for the  
correction of Presbyopia**

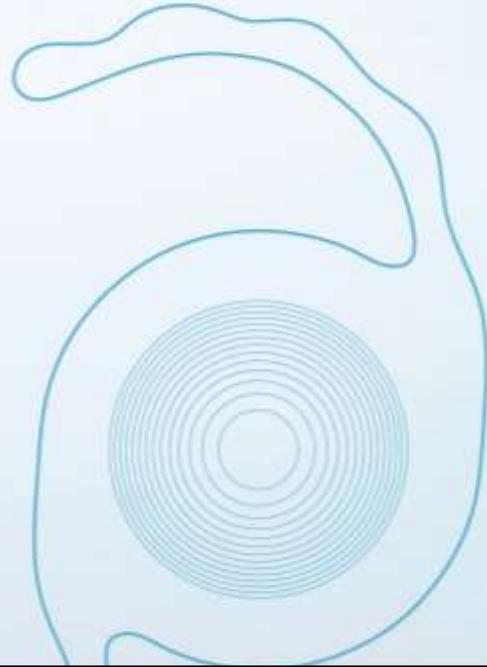
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**SULCOflex**  
TRIFOCAL



**Introducing Sulcoflex Trifocal**

## Introduction to the Sulcoflex Concept



## Introduction to Sulcoflex: 10 years of clinical success

Aspheric



Toric



Multifocal



Multifocal Toric



In 2007, the first Sulcoflex model (Sulcoflex Aspheric) was launched that allowed surgeons to correct refractive surprises. Followed closely by lifestyle options; toric, multifocal and multifocal toric Sulcoflex IOLs.

Trifocal



## Sulcoflex for Safety

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**SULCOflex**  
ASPHERIC

**SULCOflex**  
TORIC

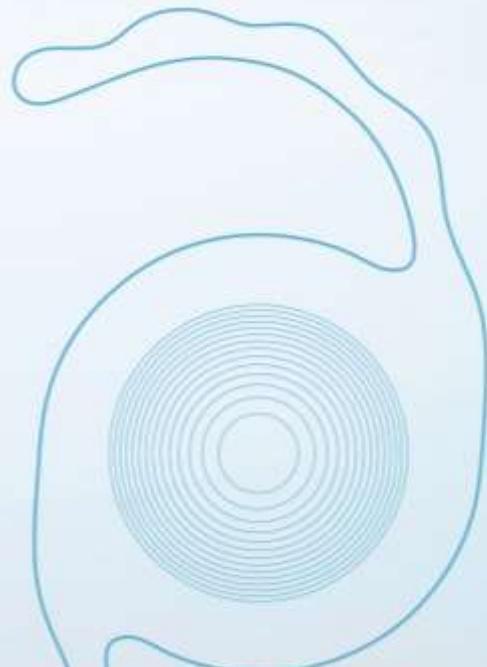
Sulcoflex was originally created as an option for refractive enhancement of satisfactory, monofocal post-operative vision after cataract surgery. As such, the primary consideration when designing the Sulcoflex platform was to create a **safe** IOL that surgeons would be confident to use.

The influences on the design of Sulcoflex were:

- The problems associated with IOL "Piggybacking"
- The risk of elevated IOP associated with a second lens in the eye
- The risk of inflammatory response associated with the placement of a lens in the sensitive ciliary sulcus.

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## Features and Benefits of the Sulcoflex Platform



## Features of The Sulcoflex Platform

### Large, 6.5mm round-edged optic, designed to:

- Reduce the risk of pupillary block and photic effects
- Reduce risk of optic-iris capture<sup>1</sup>
- Minimise edge glare
- and associated dysphotopsia<sup>1</sup>

### Rayacryl Material for:

- Good uveal Biocompatibility<sup>7</sup>
- Superb optical clarity – no vacuoles or glistenings<sup>8</sup>



### Large 14.0mm overall length with undulating haptics:

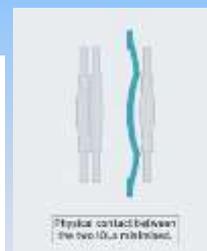
- Designed for stable fixation in the ciliary sulcus
- Unique undulating round edge haptic design with 10° angulation
- Excellent centration stability compared to capsular bag fixated multifocal IOLs<sup>5</sup>
- Reduced risk of uveal contact and abrasion<sup>1</sup>
- Reduced Pigment Dispersion Syndrome<sup>1</sup>
- Smooth undulating haptics to minimise the risk of adverse tissue reaction in the sulcus

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## Sulcoflex IOL Designed to avoid the potential problems of conventional “piggy-back” IOLs

- Unique posterior concave surface minimises the possibility of interaction with the primary IOL
- Reduced likelihood of unwanted photopic effects
- Reduced refractive error with hyperopic defocus



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## Sulcoflex design features

Feature	Purpose	Significance
Rayacryl hydrophilic acrylic material	Compatible with eye tissues – avoids ocular inflammation and irritation	Good uveal biocompatibility of Rayacryl makes the material ideal for long-term patient safety and outcomes
Large 6.5mm diameter optic	Avoids optic capture, pupillary block and photic phenomena	Reduction in risk of Glaucoma. Optic edge outside max pupil diameter.
Haptic Undulations	Promotes stability in the sulcus	Long-term refractive results depend on centration and rotational stability especially in the case of toric and multifocal lenses.

## Sulcoflex design features

Feature	Purpose	Significance
Overall length of 14.0 mm	Encourages stable positioning in the sulcus	The lens needs to be stable to offer the patient reliable and dependable results
Convex/Concave Optic configuration	Ensures no contact between the posterior surface of the supplementary IOL and the anterior surface of the primary IOL	Contact between the two lens surfaces may result in the growth of interlenticular membranes and a hyperopic defocus effect
10° Haptic Angulation	Maintains adequate distance between anterior surface of the supplementary IOL and the posterior surface of the iris	Iris chafe, abrasion or pigment dispersion are risk factors for glaucoma



## Rayner Sulcoflex® Trifocal: An elegant solution for the correction of presbyopia

The Situation

As a cataract and refractive surgeon, achieving the best possible visual results for our patients is paramount. However, challenging patients may expect more, and demand a chance of being spectacle free.

The Solution

The Sulcoflex Trifocal supplementary IOL is an adjustable option which allows us to treat an even wider range of patients for presbyopia, to meet both their visual and lifestyle needs. The Sulcoflex **DUET** procedure involves the sequential implantation of a primary capsular bag IOL and a supplementary Sulcoflex sulcus IOL. This is done as a planned DUET procedure during the initial cataract surgery.

## A proven optic design for comfortable transition from near to distant visual ranges

Indications <sup>1,4</sup>	
For pseudophakic patients with a primary capsular bag IOL.	
<ul style="list-style-type: none"> <li>✓ Presbyopia (DUEF procedure)</li> <li>✓ Pseudophakic presbyopia* (secondary enhancement)</li> </ul>	<ul style="list-style-type: none"> <li>✓ Post-surgical ametropia</li> <li>✓ Patients experiencing a dynamic change of refraction</li> </ul>

\*Contraindicated for implantation into eyes with multifocal capsular bag IOLs.

## When considering your options to treat presbyopia, what's important to you?

- ✓ Exceptional light usage
- ✓ Ease of Use<sup>2</sup>
- ✓ Efficacy & patient outcomes<sup>2</sup>
- ✓ Versatility to treat a wider range of patients<sup>3</sup>
- ✓ An adjustable solution for peace of mind
- ✓ Increased accuracy with quarter dioptre steps



## With the Rayner Sulcoflex® platform, you can expect the following:

### Predictability

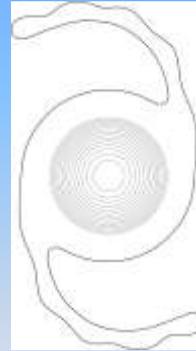
- Proven to provide better centration compared to capsular bag multifocal IOLs
- Predictable refractive outcomes; high visual acuity

### High patient satisfaction

- Low complication rate
- Stable long-term refractive results

### Reduced surgical risk associated with IOL exchange

- Less surgical trauma than primary IOL exchange
- Avoids sometimes difficult removal of fibrosed, fixated primary implant
- Allows for implantation reversibility



## Exploiting the benefits of **reversibility** and **adjustability**.

### Why adjustability

Unlike capsular bag multifocal IOLs or refractive laser treatments, the Sulcoflex Trifocal DUET procedure is easily reversed. **Refractive change or surprise cannot be predicted, and nor can a failure to neuroadapt.** Through the DUET procedure, the optic system can be easily adjusted with a different Sulcoflex Trifocal or converted back to monofocality in a straightforward procedure.

- Plan for excellence with a simultaneous implantation
- Treat ametropia after cataract surgery
- Reversible – more flexibility for surgeon and patient

## The convenience of DUET



- The Sulcoflex DUET procedure empowers surgeons with the ability to offer refractive treatments to their patients without needing to invest in expensive laser equipment.
- This cost-efficient treatment option can easily be incorporated into any existing cataract surgery environment.
- The DUET is an easy procedure, adding little time to the overall cataract surgery, and yet offers an elegant adjustable solution.

## HOW TO DUET

The Sulcoflex Trifocal is specifically for pseudophakic patients following the implantation of a primary monofocal or monofocal toric capsular bag IOL. During the DUET procedure, the capsular bag IOL is implanted first and treats the sphere -- and where required cylinder -- correction power for distance vision. Then a plano Sulcoflex® Trifocal is implanted which features the Rayner trifocal optics with a +3.50 D add for near and +1.75 D add for intermediate vision. Combining the two lenses provides the patient with an opportunity for a spectacle free solution.



## The simplicity of Sulcoflex® removal

A Sulcoflex IOL is not **explanted**; it is **removed** from the eye, often via the original cataract surgery incision.



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## The Sulcoflex Trifocal Diffractive Step Technology



## Improved visual outcomes designed for less pupil dependency

Sulcoflex® Trifocal has fewer rings on the IOL optic surface than many trifocal IOLs for **reduced potential visual disturbances and improved night vision.**

### Optic Surface Features:

- 16 diffractive steps / rings
- 4.5 mm diffractive trifocal zone
- > 4.5 mm monofocal distance zone
- Smooth anterior surface to minimise iris chafe

### Benefits:

- Reduces visual disturbances
- Developed to be less dependent on pupil size or lighting conditions
- Improves distance vision in mesopic conditions



Increased accuracy with quarter dioptre steps.

## Exceptional Light Transmission

Diffractive step trifocal technology reduces **light loss to only 11%**

- It transmits 89% of light to the retina with a pupil of 3 mm
- Allocates half the light for distance
- Divides the rest between near and intermediate vision
- Light Energy Split at 3.0 mm pupil
  - 52% Distance
  - 22% Intermediate
  - 26% Near



## Comfortable transition from near to distance activities

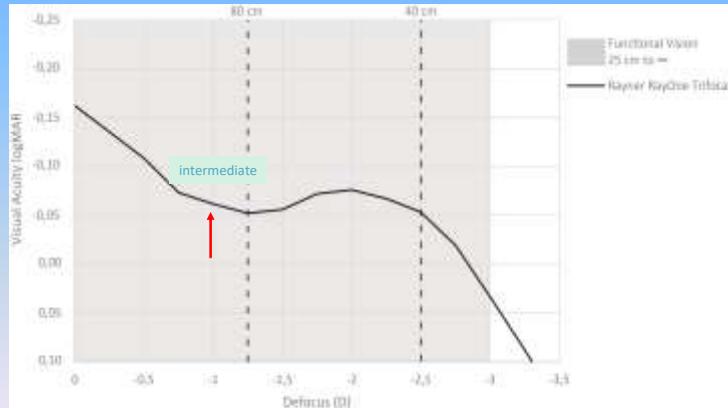
Sulcoflex Trifocal has been designed according to the optic principles of RayOne Trifocal:

**+3.50 D near add**

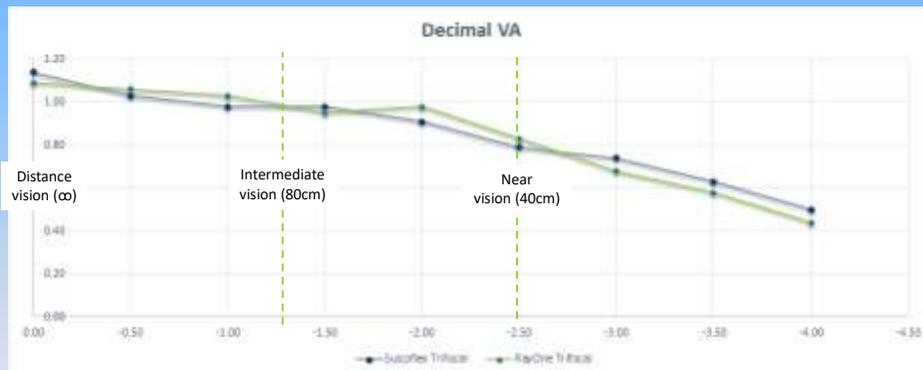
- 37.5 cm reading plane

**+1.75 D intermediate add**

- 75.0 cm reading plane



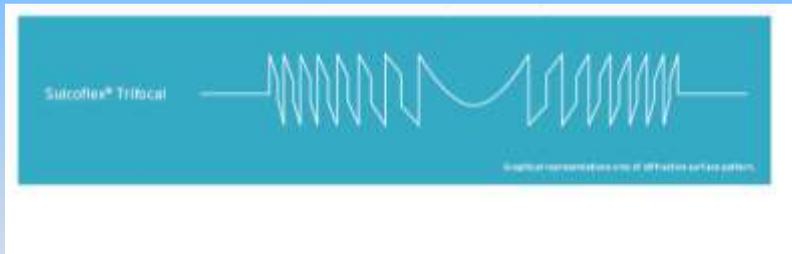
## First Visual Acuity data of Sulcoflex Trifocal comparison to RayOne Trifocal



Unpublished data provided by Professor M. Amon, Vienna, Austria. 09/2018

## Optimised diffractive design

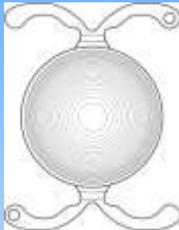
Diffractive profile is a construct of two profiles :



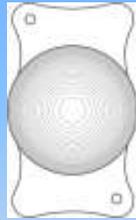
## Sulcoflex Trifocal vs other Trifocal IOLs



## Comparison of Trifocal Technologies



PhysIOL  
FineVision



Zeiss  
AT LISA Tri



Alcon  
PanOptix



Rayner  
RayOne Trifocal



Rayner  
Sulcoflex Trifocal



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Competitor Source: Respective owners published marketing materials, graphical representations only of lenses

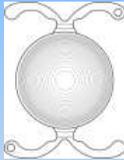
## Comparison of Trifocal Technology

	PhysIOL FineVision	Zeiss AT LISA Tri	Alcon PanOptix	RayOne Trifocal	Sulcoflex Trifocal
Diffractive Technology	Diffractive Apodized Trifocal across full optic surface	Diffractive Trifocal up to 4.34 mm thereafter bifocal	Diffractive Trifocal up to 4.5 mm thereafter monofocal	Diffractive Trifocal up to 4.5 mm thereafter monofocal	Diffractive Trifocal up to 4.5 mm thereafter monofocal
Diffractive Steps	26 diffractive steps	29 diffractive steps 0.0 D	15 diffractive steps	16 diffractive steps	16 diffractive steps
Diffractive Orders	0, 1, 2	0, 1, 2	0, 2, 3 (non sequential)	-1, 0, 1	-1, 0, 1



## Comparison of Trifocal Technology

PhysIOL  
FineVision



Zeiss  
AT LISA Tri



Alcon  
PanOptix



Rayner  
RayOne  
Trifocal



Rayner  
Sulcoflex Trifocal



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Diffractive Orders	0, 1, 2	0, 1, 2	0, 2, 3 (non sequential)	-1, 0, 1	-1, 0, 1
Light Loss 3.0 mm pupil	14%	14.3% (Ave.)	12%	11%	11%
Light Energy Split 3.0 mm pupil	49% D / 18% I / 34% N	50% D / 20% I / 30% N	50% D / 25% I / 25% N	52% D / 22% I / 26% N	52% D / 22% I / 26% N

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All trademarks are property of their respective owners  
Competitor Source: Respective owners published marketing materials

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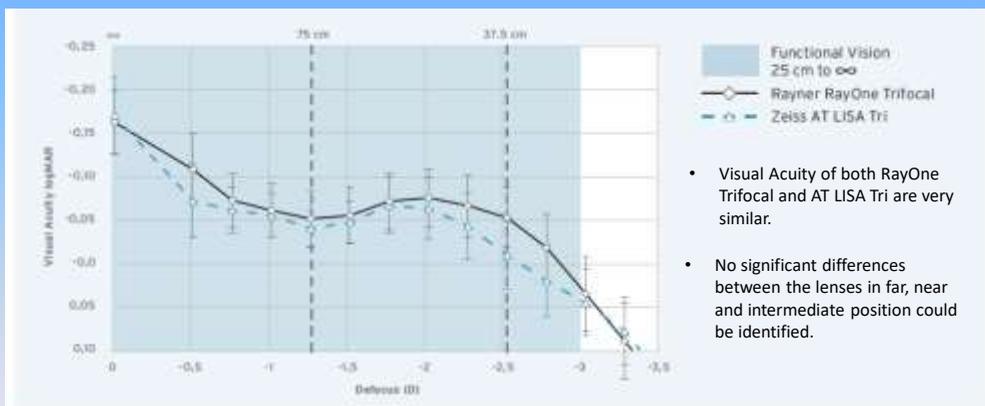
## USAF 1951 target charts



## Comparison of Trifocal Technology

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Diffractive Orders	0, 1, 2	0, 1, 2	0, 2, 3 (non sequential)	-1, 0, 1	-1, 0, 1
Light Loss 3.0 mm pupil	14%	14.3% (Ave.)	12%	9%	9%
Light Energy Split 3.0 mm pupil	48% D / 16% I / 34% N	50% D / 20% I / 30% N	50% D / 25% I / 25% N	52% D / 22% I / 26% N	52% D / 22% I / 26% N
Optic Add Powers	+3.50 D Near add +1.75 D Intermediate add	+3.33 D Near add +1.66 D Intermediate add	+3.25 D Near add +1.62 D Intermediate add	+3.50 D Near add +1.75 D Intermediate add	+3.50 D Near add +1.75 D Intermediate add
Reading Distance	37.5 cm 75.0 cm	40.0 cm 80.0 cm	42.0 cm 60.0 cm	37.5 cm 75.0 cm	37.5 cm 75.0 cm

## Comfortable transition from near to far



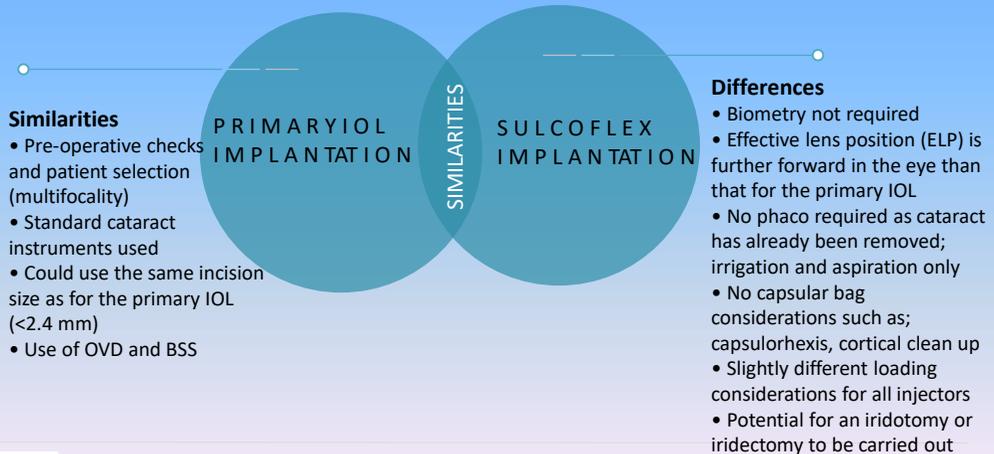
	PhysIOL FineVision	Zelux AT LISA Tri	Alcon PanOptix	RayOne Trifocal	Sulcoflex Trifocal
					
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Optic Add Powers	+3.50 D Near add +1.75 D Intermediate add	+3.33 D Near add +1.66 D Intermediate add	+3.25 D Near add +2.17 D Intermediate add	+3.50 D Near add +1.75 D Intermediate add	+3.50 D Near add +1.75 D Intermediate add
Reading Distance	37.5 cm 75.0 cm	40.0 cm 80.0 cm	42.0 cm 60.0 cm	37.5 cm 75.0 cm	37.5 cm 75.0 cm
Aberration correcting	Biconvex aspheric (-0.11 SA)	Aberration correcting (-0.20 SA)	Aberration correcting (-0.20 SA)	Aberration Neutral	Aberration Neutral
Lens Material	Hydrophillic	Hydrophillic	Hydrophobic	Hydrophillic	Hydrophillic
Dioptre range	+6.0 D to +35.0 D	+0.0 D to +32.0 D	+13.0 D to +34.0 D	+0.0 D to +30.0 D	-3.0 D to +3.0 D
Optic / Haptic Diameter	6.00 mm / 11.45 mm	6.00 mm / 11.00 mm	6.00 mm / 13.00 mm	6.00 mm / 12.50 mm	6.00 mm / 14.00 mm
Haptic design	Double C loop	Plate	C loop	Closed C loop	C loop
PCO rate (estimated by review on studies stating YAO caps rates on monofocal lenses)	Medium (24 months)	High (24 months)	Low (24 months)	Low (1.7% @ 24 months)	N/A
Filtration	UV and blue light	UV	UV and blue light	UV	UV
Angulation	5°	0°	0°	0°	10°
Injection size	Loadable	Semi preloaded	Loadable	Preloaded	Loadable
Nozzle Tip Size	1.74 mm	1.65 mm	2.0 mm x 1.5 mm	1.65 mm	1.65 mm
Incision Size (wound in)	2.4 mm	2.2 mm	2.4 mm	2.2 mm	2.2 mm

## The Sulcoflex Procedure, Biometry and Implantation



## Pre-operative Preparation for Sulcoflex

The implantation of a Sulcoflex is a significantly different procedure to that for a primary capsular bag IOL.



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## Summary



## Rayner's Most Technologically Advanced IOL

Proven  
Sulcoflex  
Platform

Trifocal  
Technology

The Sulcoflex Trifocal combines Rayner's pseudophakic supplementary Sulcoflex platform – designed to be implanted in the ciliary sulcus – with the patented trifocal optic technology of the recently launched RayOne Trifocal IOL.

### Diffraction step trifocal technology reduces light loss to only 11%

- 89% of light transmitted to the retina with a pupil of 3 mm
- Half the light allocated for distance
- Remaining light divided between near and intermediate vision
- Light Energy Split at 3.0 mm pupil
  - 52% Distance
  - 22% Intermediate
  - 26% Near

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## New Sulcoflex Trifocal IOL. An elegant solution for the correction of presbyopia

The **World's First** trifocal supplementary lens

- ☑ Works with any monofocal or toric primary IOL
- ☑ Adjustable solution that allows you to treat an even wider range of patients that desire a spectacle free lifestyle
- ☑ Available in 0.25 Dioptre increments from -1.0 to + 1.0
- ☑ Sulcoflex is a proven supplementary platform with over 10 year's clinical data and is also available in Aspheric and Toric variants



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## The benefits of Sulcoflex



SAFETY

ADJUSTABILITY

OPPORTUNITY

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## Technical specification

Model Name:	Sulcoflex® Trifocal
Model Number:	IOL703F
Power Range:	-3.0 D to +3.0 D (increments 0.5 D), -1.0 D to +1.0 D (increments 0.25 D) Trifocal, diffractive, +3.5 D near add and +1.75 D intermediate add at the IOL plane.
<b>Aspheric Trifocal IOL</b>	
Material:	Single piece Rayacryl® hydrophilic acrylic
Water Content:	.26% in equilibrium
UV Protection:	Benzophenone UV absorbing agent
UV Light Transmission:	UV 10% cut-off is 380 nm
Refractive Index:	1.46
Overall Diameter:	14.00mm
Optic Diameter:	6.50mm
Optic Shape:	Anterior convex, posterior concave
Asphericity:	Aberration-neutral technology
Haptic Angulation:	10° Posterior angulation
Haptic style:	Undulating and rounded C-loop haptics
Estimated constant for power calculation	Expected lens position = 4.5 mm

**Muchas Gracias**

