Sulcoflex Pseudophakic Supplementary IOLs

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The Sulcoflex range is available in the following presentations:
• IOL only

Sulcoflex intraocular lenses (IOLs) are high precision single piece optical devices, manufactured from Rayacryl (hydroxyethyl methacrylate/methyl methacrylate copolymer). Sulcoflex IOLs are intended for refraction adjustment of the pseudophakic eye following a primary IOL implantation into the capsular bag. They are designed with a rounded optic and rounded haptics for secondary implantation into the ciliary sulcus of the eye.

The Aspheric model is intended to provide adjustment to the dioptric power of the eye. The Toric model is intended to provide adjustment to astigmatism and the dioptric power of the eye. The Trifocal model is intended to provide pseudo accommodation and adjustment to the dioptric power of the eye.

Note: Pseudo accommodation is achieved using diffractive optics to create simultaneous multiple images on the retina of distant, intermediate and near objects.

IOL Material (Rayacryl) Characteristics

- Water content: 26% in equilibrium
- Refractive index: 1.46
- UV light transmission: shown in Figure 1 (UV 10% cut-off is 380 nm)
- Nd: YAG laser compatible

Indications

Pseudophakic patients with a primary capsular bag fixated intraocular lens, requiring a refraction adjustment by a secondary lens implantation into the ciliary sulcus.

Contraindications

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

- Microphthalmia
- Corneal Oedema
- Pars Planitis
- Pseudo exfoliation
- Active ocular diseases (e.g. chronic severe uveitis, proliferative diabetic retinopathy, chronic glaucoma not responsive to medication)
- Corneal decompensation or endothelial insufficiency
- Children under the age of 18 years
- Shallow anterior chamber
- Pseudophakic patients with a malpositioned or unstable capsular bag fixated intraocular lens
- Inability to secure placement in the designated location e.g. the absence of a secure peripheral anterior capsule, the absence of intact zonules, unusual or irregular anatomy of the ciliary sulcus

Additionally for Trifocal IOLs:

- Patients with ocular disorders, other than cataract, that could potentially cause future acuity losses to a level of 20/30 or worse in either eye
- Patients who are expected to require retinal laser treatment
- Patients unlikely to achieve less than 1.5 Dioptres of post-operative astigmatism
- Patients unlikely to adapt to simultaneous multiple retinal images
- Patients with a multifocal capsular bag fixated IOL

Adverse Events

Cataract surgery for IOL implantation presents risks which the surgeon must evaluate. Potential complications of cataract surgery are;

- Secondary glaucoma
- IOL replacement or extraction
- Precipitates
- Reduced vision
- Vitreous herniation
- Excessive intraoperative vitreous loss
- IOL decentration
- Secondary membrane
- Expulsive haemorrhage
- IOL dislocation and subluxation
- Retrolenticular membrane
- Corneal oedema
- Endophthalmitis and panophthalmitis
- Retinal detachment
- Corneal dystrophy
- Haemorrhage
- Iris atrophy
- Pupillary block
- Cystoid macular oedema
- Severe ametropia and aniseikonia
- Iridocyclitis and hyalitis
- Deviation from target refraction
- Fibrin reaction

⚠ Warnings

- Unusual or irregular anatomy of the ciliary sulcus may cause a post-operative rotational displacement of the IOL. In such cases, the IOL may be realigned and fixated by suture.
- An iridotomy/iridectomy may be necessary
- Single use IOLs and single use injectors cannot be reused, as it is not designed to perform as intended after the first and only usage. Changes in mechanical, physical or chemical characteristics, under conditions of repeated use, cleaning and resterilisation, will compromise the integrity of IOLs and injectors.

A risk/benefit analysis must be performed before confirming a patient as a candidate for a Rayner IOL, if they are suffering from any of the following conditions:

- Recurrent ocular disease (e.g. uveitis, diabetic retinopathy, glaucoma, corneal decompensation)
- Previous ocular surgery
- Vitreous loss
- Iris atrophy
- Severe aniseikonia
- Ocular haemorrhage
- Macular degeneration
- Zonular dehiscence (for patients at risk of zonular dehiscence, it is recommended that a capsular tension ring (CTR) is inserted to support the capsular bag).
- Ruptured posterior capsule
- Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.
- 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).
- A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
- Circumstances that would result in damage to the endothelium during implantation.
- Suspected microbial infection
- Non-toothed, polished instruments must be used if handling the IOL.
- Do not allow the IOL to dehydrate during the procedure.
- Do not use balanced salt solution (saline) as the sole lubricating agent, always use in combination with an ophthalmic viscosurgical device (OVD).
- Do not attempt to disassemble, modify or alter this device or any of its components, as this can significantly affect the function and/or structural integrity of the design.

Precautions

- The sterility of the contents is guaranteed only if the outer tray has not been opened or damaged.
- Do not use if the pack has been damaged.
- Do not store in direct sunlight.
- Do not store the pack outside of the recommended storage conditions; store between 0°C to 45°C.
- Do not store below 20% Relative Humidity.
- Do not use after the expiry date.
- Do not attempt to reuse this device.
- Do not resterilise.

Sterilisation and Packaging

The IOL is supplied sterile in a sealed blister pack containing 0.9% saline solution. The sterilised blister pack is steam sterilised and should only be opened under sterile conditions. An implant card is included in the pack to record all implant information (the supplied labels may be used). It shall be given to the patient, with the instruction to keep this card. The card should be shown to any eye care professional the patient visits in future.

Directions for Use

Only those injectors validated for use with the Sulcoflex range should be used for the placement of Sulcoflex IOLs into the eye (please refer to www.rayner.com or speak to your Rayner Representative). To ensure optimum injection performance of the IOLs, the blister pack should be allowed to equilibrate to a temperature of 21ºC or above before use (equilibration takes approximately 30 minutes from an initial temperature of 0ºC). Load the injector under well lit conditions or using magnification. The use of a sodium hyaluronate-based OVD is recommended.
Load the lens into the injector immediately after removal from the blister pack and insert into the eye within 3 minutes of loading. For loading details, refer to the 'Loading Instructions' section of this IFU.

IOL Placement

The surgeon should ensure that the lens is implanted into the ciliary sulcus with the correct anterior / posterior orientation and (if toric) is placed with the correct rotational orientation. Correct anterior / posterior placement is achieved when the haptics sweep away from the optic in a counter-clockwise direction (anterior view). This means that the IOL can most easily be dialed clockwise as is usual for posterior chamber IOLs. The lens should therefore be positioned in the injector loading bay a "reverse - S configuration". Correct rotational orientation of toric IOLs is achieved when the IOL's axis marks (the lowest IOL power meridian) align with the spectacle prescription plus cylinder axis.
Note: For the Sulcoflex Toric, the axis marks are on the posterior lens surface.

Fig 3
Haptic Orientation

Loading instructions

Step 1 Aseptically transfer the injector to the sterile field by tipping it from the tray. Fully retract the plunger ensuring that the soft tip does not protrude into the loading bay.

Step 2 Open the loading bay flap fully and apply OVD inside the nozzle and to both grooves of the loading bay.

Step 3 Carefully peel back the foil lid of the lens blister. Gently lift out the lens using parallel tipped, non-serrated forceps e.g. Kelman-Mcpherson. Rinse the lens with sterile balanced salt solution.

Step 4 Position the lens centrally in the loading bay in a "reverse - S" configuration. Ensure that the nearest edge of the optic is securely under the edge (lip) of the loading bay as shown.

Step 5 Hold open the flap and gently press down on the lens with closed forceps to ensure the furthest edge of the optic is securely under the edge (lip) of the flap as shown (A). Ensure the haptics are also securely under the edges within the loading bay (B and C)

Step 6 **Ensure that NO parts of the optic or haptics of the lens are projecting outside the edges of the loading bay.** While keeping the lens in position with open forceps and placing gentle down pressure on the optic, carefully close the flaps of the injector locking them firmly together. Any resistance could indicate a trapped lens.

Step 7 Ensure that no parts of the optic or haptics are trapped between the flaps. Advance the plunger in a slow and controlled manner. Anticipate an initial slight resistance. Excessive resistance could indicate a trapped lens. If excessive resistance is felt, fully retract the plunger and then advance until in contact with the lens again. If the lens causes a blockage in the injector system, discard the injector.

Step 8 Continue the injection in a **slow and controlled manner.** Do not exert excessive force on the plunger. When the lens exits the nozzle, stop depressing the plunger and do not retract the plunger. Discard the injector after use.

Calculation of IOL Power

The surgeon should preoperatively determine the power of the IOL to be implanted. This can be calculated variously from the biometry and refraction 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, 1988
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