

	MINI 4 YELLOW Ready PRODUCT TECHNICAL SHEET	Rev. 4.0 Revision date: 03/2021
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MINI 4 YELLOW Ready



1. Trade Name

MINI 4 YELLOW Ready is a kit composed by an acrylic aspherical intraocular lens (EC 0123) and a dedicated injection system (EC 0482).

MINI 4 YELLOW Ready Series Code: Y/W7560CY

Individual Product Code:

MINI 4 Yellow Ready: Y7560CYPXXXXA biconvex IOL (Dioptric Range $+30.0D \div 0.0 D$),
where:

P = positive dioptric power

XXXX = dioptric power between 00.00 and 30.00

MINI 4 Yellow Ready: W7560CYNXXXXA concave convex IOL (Dioptric Range $-1.0 D \div -10.0D$),
where:

N = negative dioptric power

XXXX = dioptric power between -10.00 and -1.00

2. Manufacturer

IOL: SIFI S.p.A.

Via Ercole Patti, 36
95025 - Aci S. Antonio (CT) – Italy

INJECTOR: Medice AG

Dornierstrasse 11
CH-9423 Altenrhein – Switzerland

3. EC Marking

IOL: EC 0123

INJECTOR: EC 0482

4. Compliance

Legislative Decree 46/97 (Medical Device Directive 93/42/CEE)

EN ISO 13485:2016 Medical Devices, Quality Management Systems - Requirements for Regulatory Purposes

UNI EN ISO 9001:2015 Quality System - Requirements



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5. European Classification

IIb

6. General Product Description

The one-piece UV-A absorbing foldable intraocular lenses MINI 4 YELLOW Ready are optical implants for the posterior chamber that can be implanted in the capsular bag to replace the human crystalline lens in the correction of aphakia in adult patients. These pre-loaded intraocular lenses are specific to the mini-incision surgical technique.

Their material "Natural Yellow" has a UV-A Blocking and Violet Light filtering chromophore that is in the human crystalline lens.

MINI 4 YELLOW Ready IOLs have a biconvex optical shape for dioptric powers from 0 to +30 and a reverse meniscus optical shape for dioptric powers from -10.0 to -1.0.

The anterior aspherical optical surface is designed to reduce optical aberrations.

The posterior surface has a double square edge which is intended to reduce the incidence of posterior capsule opacification.

This surgical medical device is a system consisting of an intraocular lens and a disposable injector pursuant to Directive 93/42 EC.

Physical Characteristics:

Water content	25%	
Refractive Index	at 35 °C (in hydrated state)	1.46

Range of Dioptric Powers:

Lens model	Min. Power (D)	Max. Power (D)	Incremental Step (D)	Incremental Step (D)
MINI 4 YELLOW Ready	-10.0	+30.0	0.5 from +10.0 to +30.0	1.0 from -10.0 to +10.0

Technical Characteristics:

Lens model	Optical plate diameter (mm) Ø _P	Total Diameter (mm) Ø _T	N. of haptics	Angle of the haptics
MINI 4 YELLOW Ready	6.0	10.75	4	5°

Lens model, dioptric power, suggested A constant and main dimensions (diameter of the optical plate, total diameter, angle of the haptics) are stated on the case and on the primary and secondary packages.

7. Composition/Material/Technical Characteristics

The intraocular lenses MINI 4 YELLOW Ready are made of a hydrophilic - hydrophobic copolymer that includes 2-HEMA (2-hydroxyethyl methacrylate) and EOEMA (2-ethoxyethyl methacrylate) with ultraviolet absorber and a refractive index of 1.46 at 35° C.

2-HEMA is a hydrophilic monomer. Conversely, EOEMA is a hydrophobic monomer. Two monomers combined form an acrylic copolymer with higher refractive index and improved mechanical properties compared to single monomers.

Furthermore, the polymer is ultrapure, i.e. without any residual acid, with zero ionicity thus excluding any possibility that the lens might become opaque due to calcium deposits.



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8. Indications

MINI 4 YELLOW Ready aspheric IOLs are intended for primary implantation for visual correction of aphakia in adult patients after removal of a cataractous lens. These implants must be positioned within the capsular bag.

9. Instructions for use

1. Appropriate implant selection
 - a. Examine the label of the complete package to verify the model, dioptric power or spherical equivalent, design and date of expiration of the product.
 - b. Suggested constant A: the constant A on the package is intended as a guideline and starting point for calculating the dioptric power of the implant. We suggest that surgeons should develop the constant value based on their clinical experience.
2. Removing the implant from its package
 - a. After opening the case, check that the information on it corresponds to that listed on the label in the lens package.
 - b. Open the lens external package and transfer the lens container in the sterile field in accordance with good practices in sterile field management.
 - c. Open the injector blister and place it on the sterile operating table.
 - d. Carefully open the lens container and remove the loading chamber in which it is lodged.
 - e. Insert the loading chamber holding the IOL into the specific injector slot.
 - f. Apply viscoelastic solution first through the front hole until the tip is filled and then through the rear hole towards the back of the chamber until the solution comes out, in order to obtain a barrier between lens and silicone cushion.
 - g. In addition, apply a drop of viscoelastic solution on the tip of the silicone cushion. It is recommended to use the SIFI viscoelastic solution, in order to allow the correct lens injection procedure.
 - h. Carefully remove the loading chamber block by lifting it from below with thumb finger and holding the upper part with index and middle fingers. Check that the lens is located at the centre of the loading chamber. Close the cartridge sides together until the "click-lock" mechanism engages.
 - i. Push forward the plunger softly and ensure that the silicone cushion correctly enters the loading chamber. Continue to push the plunger bringing the lens toward the tip of the injector. In the event the lens-injector system gets jammed, stop using the device.
3. Lens Injection
 - a. Introduce the injector tip, with the slanting side pointing downwards, into the tunnel and inject the intraocular lens into the bag.
 - b. After the injection, pull out the injector from the incision.

Attention: When the loading chamber is introduced into the injector, the plunger should be in the pulled-back position. The injector tip must be handled with care, especially during insertion of the loading charge into the injector. It must not be damaged in order not to jeopardise the injection operation.

10. Sterilisation

The intraocular lens package consists of a double-barrier steam-sterilised assembly; the injector and the blister in which it is lodged are sterilised with ethylene oxide.

Steam sterilisation is compliant with standard UNI EN ISO 17665-1.

11. Packaging

MINI 4 YELLOW Ready lenses are supplied in a hydrated state. The package consists of a double sterile barrier film.



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The primary package of this IOL consists of a plastic container sealed by an aluminum foil containing a specific loading chamber where the IOL is inserted. The plastic container is filled with a sterile and apyrogenic saline solution. The plastic container is packaged in turn in a pouch.

The primary package of the injector consists of a Tyvek blister.

The case representing the SKU contains the lens and its injector, the "Product Information" leaflet, the implant card and the labels with the lens ID information.

12. Warnings

1. Patients with one or more of the following conditions are not eligible candidates for implantation of a intraocular lens, as it can worsen the pre-existing condition, interfere with diagnosis or the treatment of a condition or potentially be a risk for the patient's sight:
 - a. zonular laxity
 - b. irregularity and decentration of capsulorhexis
 - c. recurrent inflammation of anterior or posterior segment of unknown etiology (chronic uveitis)
 - d. patients in whom the intraocular lens might interfere with the ability to observe, diagnose or treat posterior segment conditions
 - e. intraoperative challenges which could increase the risk of complications, such as severe bleeding, significant iris damage, uncontrollable elevated intraocular pressure or significant vitreous loss
 - f. lack of capsular support for implantation of the intraocular lens in the capsular bag
 - g. decompensated glaucoma
 - h. dystrophy of corneal endothelium
 - i. proliferative diabetic retinopathy
 - j. microphthalmus
 - k. pediatric patients
 - l. suspected microbial infection
 - m. patients without an adequate support for the lens from the posterior chamber or the zonule
 - n. bilateral congenital cataracts
 - o. history of retinal detachment or susceptibility to this condition
 - p. monocular patients
2. MINI 4 YELLOW Ready IOLs must be positioned within the capsular bag and not in the ciliary sulcus.
3. Carefully remove all viscoelastic material from the capsular bag.
4. Other potential complications following IOL implantation are correlated to cataract surgery.

13. Precautions for use

1. The recent use of contact lenses affects the patient's refraction; therefore, in those wearing contact lenses, surgeons must define corneal stability without contact lenses before determining the power of the intraocular lens.
2. Do not re-sterilise the intraocular lens.
3. Do not reuse the intraocular lens; reuse compromises the sterility of the implant.
4. Do not use the system if the package is damaged or open.
5. Do not use after the expiration date printed on the package.
6. Do not use balanced saline solutions, Ringer lactate and/or hydroxypropyl methylcellulose during the loading procedures of the lens into the injector.
7. Improper handling of the preloaded system as well as improper bending techniques may cause damage to the haptics and/or the optical part of the lens. The surgeon must not attempt to implant lenses with a damaged optical plane or haptics. For a correct handling of the medical device follow the instructions for use being provided.
8. The intraocular lens implant requires adequate surgical skills.
9. Opening the protective packaging requires immediate use of the intraocular lens to prevent contamination or dehydration.
10. MINI 4 YELLOW Ready intraocular lenses must be kept at room temperature. It is recommended to implant them after keeping them at least 60 minutes at the temperature of the operating room. In this way it is possible to avoid that the thermal shock, resulting from an abrupt exposure to body temperature, causes a transient loss of transparency of the device.



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11. MINI 4 YELLOW Ready intraocular lenses by SIFI S.p.A. are compatible with the Accuject Pro 1.8-1P injector with which they are supplied (Incision size: Wound-assisted technique: 1.8 mm; Into-the-wound technique: 2.0 mm; Into-the-bag technique: 2.2 mm).
Intraocular lenses that are not compatible may be damaged by the injector and therefore do not use the injector with lenses other than those suggested.

14. Adverse events

The potential adverse events that may occur during or after cataract surgery with implantation of an intraocular lens may include but are not limited to:

General adverse events for intraocular lenses

1. Residual refractive error
2. Increase of intraocular pressure
3. Corneal edema
4. Inflammation (Endophthalmitis, Iropion, Cystoid macular oedema)
5. Pupillary block
6. Retinal detachment
7. Displacement of the intraocular lens (Tilt and decentralisation)
8. Secondary surgical intervention (including repositioning of the implant, removal and replacement, PCO, or other surgical procedure)
9. Any other adverse event that leads to permanent damage to eyesight or requires surgery or a doctor to avoid this epilogue.

15. Safety Information

MINI 4 YELLOW Ready intraocular lenses do not contain latex or phthalates.

16. Compatibility with other products

There are no interactions between the intraocular lens and other devices or therapies.

17. Validity

4 years.

18. Storage and Handling Conditions

Store at room temperature.

If the lenses are exposed to temperatures other than those shown in the case, it is recommended to stabilize them at the operating room temperature at least 60 minutes before the implant.

19. Disposal

No special precautions are required for disposal.

END OF DOCUMENT

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