PRODUCT INFORMATION
Medical product «Intraocular Lens NanoCrystals» Aquamarine model

ТУ 9398-001-16419445-2015

1. GENERAL INFORMATION

Intraocular lens (IOL) NanoCrystals Aquamarine is intended for optical correction of vision by the surgical insertion inside the aphakic eye in the ophthalmological hospitals and ophthalmological clinics. The product's flexibility allows placement through small incisions. A high level of surgical skill is required for intraocular lens implantation.

2. DESCRIPTION

Intraocular lens (IOL) NanoCrystals Aquamarine is an ophthalmological implant which consists of a soft acrylic material capable of being folded prior to insertion, allowing placement through small operational incisions of 2,2 mm with injector cartridge or with forceps. Posterior Chamber Intraocular Lens Aquamarine is positioned into the capsular bag, replacing the natural crystalline lens, which allows the lens to function as a refractive medium in the correction of aphakia.

3. FEATURES AND EFFECTIVENESS

Intraocular lens (IOL) NanoCrystals Aquamarine is a single-piece posterior chamber intraocular lens, which consists of image forming aspheric optical part with supporting peripheral elements – closed haptics for firm fixation and support of IOL in the capsular bag. Intraocular lens (IOL) NanoCrystals Aquamarine is made of premium quality hydrophilic acrylic with a blue light filtering. The biconvex Monofocal optic of Aquamarine IOL has a high refractive index. For the key physical characteristics of Aquamarine lens see Table 1.

Table 1. Physical characteristics of Aquamarine intraocular lens

Configuration	**Single-piece**
Optic type	**Aspheric, monofocal**
Haptic	**Closed**
Water contents	**26%**
Incision size	**2,2 mm**

Main sizes and image of the lens are shown in Table 2 and Figure 1

Table 2. Main sizes of Aquamarine lens

Lens model	Overall length	Optic diameter	Haptic angulation	Haptic thickness	Refractive index
Aquamarine	**11,00 mm**	**6,00 мм**	**0°/5°**	**0,290 mm**	**1,460 by 20°C 1,457 by 35°C**

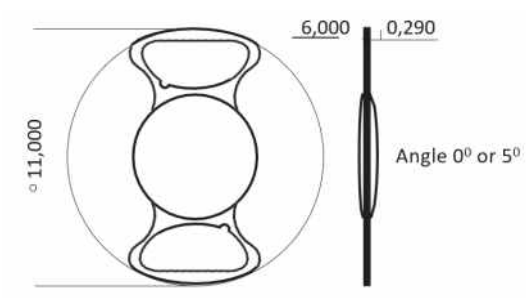

Figure 1. Main sizes and overall image of Aquamarine IOL

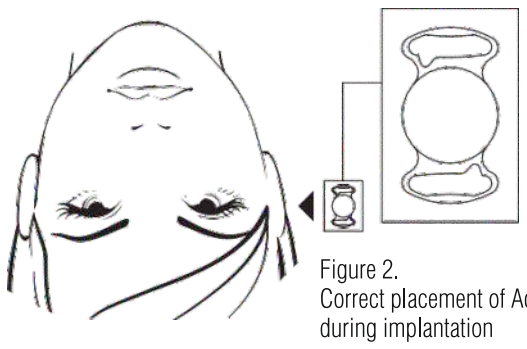

Figure 2.
Correct placement of Aquamarine IOL during implantation

Optic powers are shown in Table 3.

Table 3. Aquamarine lens optic powers

Lens model	Posterior vertex refraction (in D)
Aquamarine	**+6,00 - +35,00, step 0,50**

4. MODE OF ACTION

Posterior chamber intraocular lens Aquamarine is intended to be positioned into the capsular bag to the patients with distorted vision in cases of:

4.1 Replacement of human natural lens,
4.2 Refractional correction of vision by aphakia,
4.3 Persistent myopia,
4.4 Persistent hyperopia,
4.5 Contact lenses intolerance,
4.6 IOL use is justified by professional or other peculiarities of patent's life (refer to SAFETY RULES)

5. DIRECTIONS FOR USE

5.1 There are various surgical procedures that can be used, and the surgeon should select a procedure that is appropriate for the patient.
5.2 Before use examine the marking carefully: examine the label on the unopened package for model, spherical power and expiration date.
5.3 Check the package to make sure it is undamaged and has proper configuration.
5.4 After opening the outer polyethylene film and cardboard storage container verify lens information (e.g., model, power, serial number) on the pouch and casing is consistent with information on outer package labeling.
5.5 Open the pouch and in the sterile environment remove the case out of it.
5.6 Carefully take the lens with the forceps by the haptics and remove it from the holder. When removing the lens from the holder, do not grasp the optical area with forceps until the lens is folded.
5.7 All instrumentation should be scrupulously clean to minimize the occurrence of marks on the lens while folding. After folding, the lens should be inserted within 3 minutes.
5.8 Prior to insertion, the lens should be carefully examined under magnification. In case of any defect or deformation occurrence, the lens should be returned to the manufacturer together with the package.
5.9 Prior to insertion, the surgeon should make sure the necessary instrumentation is available.
5.10 In the capsular bag, the posterior aspheric optical surface of the lens with the sharp angle should adhere to the posterior capsule of the eye's lens. To achieve this, during insertion the lens should be positioned as follows: the haptic element, directed during the insertion of IOL to the patient's nose, should be opened to the left, the haptic element, directed to the patient's forehead, should be opened to the right. (see Figure 2).

6. PRECAUTIONS

Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with IOL's insertion. Patients with any of the below mentioned conditions are not recommended to have intraocular lens implanted, as crystalline replacement surgery might severe their present condition. As with any surgical procedure, there is risk involved. The physician must determine the benefits to be derived from lens implantation when such conditions exist:

6.1 Iris rubeosis
6.2 Hemorrhage in the choroid of the eye
6.3 Previous retinal detachment
6.4 Diabetic retinopathy
6.5 Posterior capsule rupture
6.6 Extensive detachment of ciliary zonules
6.7 Microphthalmos
6.8 Extremely shallow anterior chamber
6.9 High intraocular pressure

6.10 Glaucoma uncontrolled with medication
6.11 Age-unrelated cataract
6.12 Significant vitreous loss
6.13 Clinically severe corneal dystrophy
6.14 Clinically severe optic nerve atrophy
6.15 Extensive alterations in the macular zone
6.16 Color vision deficiencies
6.17 Acute inflammation
6.18 Recurrent iritis, uveitis
6.19 Aniridia
6.20 Single seeing eye
6.21 Accompanying general diseases, particularly non-compensated, e.g. diabetes, arterial hypertension, blood coagulation disorders, inflammation in other organs and systems, some medicines, etc.)

7. WARNINGS DURING IMPLANTATION

7.1 By wrong handing of IOL, damage of the optic and/or haptics of the lens may occur.
7.2 Potential complications accompanying implant surgery may include, but are not limited to, the following: lens repositioning, hyphema, corneal endothelial edema, corneal atrophy, iris atrophy, iris prolapse, retinal detachment, prolapse of the vitreous body, macular edema, endophthalmitis, hypopyon, glaucoma, ametropia and anisocoria, pupillary block, etc.
7.3 Any unforeseeable circumstances or difficulties during insertion may increase the risk of potential complications and adverse reactions.
7.4 For patients with pre-existing ocular conditions and intraoperative complications careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient. Alternative treatment should be considered for patients with one or more pre-existing conditions and intraoperative complications.
7.5 Patients with preoperative ocular pathology (corneal dystrophy, extensive alterations in the fundus, glaucoma, etc.) may not get high or satisfactory vision acuity after the surgery. In such cases surgeon should warn the patient about low parameters of visual functions.
7.6 In some cases, other ophthalmological surgery may be required such as access sealing, lens repositioning, lens replacement, retinal detachment manual, etc.
7.7 Prior to IOL's encapsulation patients should observe regime and be especially careful to avoid the lens' misalignment or misplacement.
7.8 Carefully remove all viscoelastic from both the anterior and posterior sides of the lens.
7.9 Surgeon should control the implant after the surgery and proceed with the patient's dynamic observation.

8. SAFETY RULES

8.1 Do not use non-sterile
8.2 Do not re-use
8.3 Do not resterilize
8.4 Do not use after expiration date
8.5 Do not use if the product or package is damaged
8.6 Do not store at temperatures >45 C or 110 F
8.7 Use only sterile balanced intraocular irrigating salt solutions
8.8 The lens requires careful handling to avoid optical surface or haptics damage
8.9 A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses

9. PATIENT INFORMATION

The patients should undergo full preoperative general and ophthalmological examination and necessary preparation.
The Patient Identification Card included in the package 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 care practitioner that the patient consults in the future.
Events that reasonably suggest that the lens may have caused or contributed to death or serious injury, including events occurring as a result of failure of a medical device to meet its performance specifications or otherwise perform as intended, should be reported to «NanOptika» LLC (Russia) or to distributors of the company's products.
Manufacturer: «NanOptika» LLC
(«NanOptika» LLC), Russia, 117342, Moscow, Profsoyuznaya str., 65, build. 1, floor 18, room XLIV office 5.02
Place of production: «NanOptika» LLC, Russia, 124460, Moscow, Zelenograd, pr. 4801, 7, build. 7 Phone: +7(495) 107-99-71
E-mail info@nanoptika.ru www.nanoptika.ru

10. EXPIRATION DATE

Sterility is guaranteed in case the package is not damage and safety and transportation rules are observed.
The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to «NanOptika» LLC (see RETURNED GOODS POLICY).

11. RETURNED GOODS POLICY

Return or exchange of NanoCrystals IOL is executed in accordance with the current legislation of Russia – law of the Russian Federation of February 7th 1992 N 2300-I "About consumers' rights protection" (with alterations of 2nd of June 1993., 9th of January 1996, 17th of December 1999, 30th of December 2001, 22nd of August, 2nd of November, 21st of December 2004., 27th of July 2006, 25th of November 2006, 25th of October 2007).
In case of any problems with IOL's usage, check your actions carefully to comply with the instruction. The manufacturer has the right to carry out the product's expertise while checking reasons for return or replacement of the product.

12. TRANSPORTATION AND STORAGE

The lens should be transported at temperatures from +0oC to +45oC and relative humidity of 30-50%.
Storage conditions – at temperatures from +0oC to +45oC and relative air humidity of 30-50%, avoiding straight sunrays.
Guarantee period of sterility is 3 years.

13. UTILIZATION

IOLs subject to utilization, damaged IOLs or their parts should be utilized as medical waste of Б class in accordance with Sanitary Rules and Norms of the Russian Federation 2.1.7.2790-10.

14. MANUFACTURER

«NanOptika» LLC, Russia, 124460, Moscow, Zelenograd, pr. 4801, 7, build. 7 Phone: +7(495) 107-99-71
E-mail info@nanoptika.ru www.nanoptika.ru

15. SYMBOLS USED ON THE PACKAGE OF THE MEDICAL PRODUCT