Bausch + Lomb Model 122LV
Cataract Anterior Intraocular Lens Family
14559/S/4003906

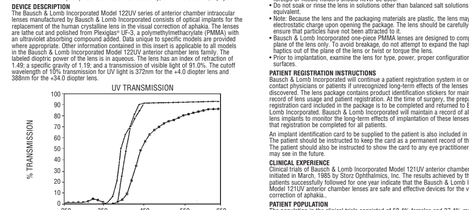
ENG

PRODUCT INFORMATION

Caution: Federal law (USA) restricts this device to sale by, or on the order of, a physician.

DEVICE DESCRIPTION

The Bausch & Lomb Incorporated Model 122UV series of anterior chamber intraocular lenses manufactured by Bausch & Lomb Incorporated are intended for optical implants for the replacement of the human crystalline lens in the visual correction of aphakia. The lenses are lathe cut and polished from Pevaloxy® UF-3, a polymethylmethacrylate (PMMA) with an ultraviolet absorbing compound added. Data using to specific models are provided where appropriate. Other information contained in this document applies to all models in the Bausch & Lomb Incorporated Model 122UV anterior chamber lens family. The lenses are offered in two styles: the lens in is aqueous. The lens has an index of refraction of 1.49; a specific gravity of 1.19; and a transmission of visible light of 91.0%. The cutoff wavelength of 50% transmission for UV light is 370nm for the 4.0 diopter lens and 368nm for the +34.0 diopter lens.



The Bausch & Lomb Incorporated Model S122UV or L122UV anterior chamber intraocular lens is a small transparent device containing a biconvex optical lens, which is designed to be implanted in the anterior chamber of the eye for the purpose of either an intra-extracapsular cataract extraction.

The flexible haptic members permit two lens sizes to fit the majority of eyes. Specifically, the 12.50mm version is designed to fit eyes with white to white measurements ranging from 10.00mm to 11.49mm and the 13.00mm version for the anterior chamber 11.50mm to 12.25mm.

The Bausch & Lomb Incorporated Model 122UV series anterior chamber lens weighs approximately 20.0mg in air and 3.3mg in situ.

Models in the Bausch & Lomb Incorporated 122UV anterior chamber lens series are available in powers (in situ) from +3.5 to +45.0 diopters in 0.5 diopter steps.

Bausch & Lomb Incorporated intraocular lenses are supplied sterile. The inner package is thermally sterilized and should be opened only under sterile conditions.

MECHANICAL CHARACTERISTICS

MODEL NUMBER	S122UV	L122UV
Overall Lens Diameter	12.5mm	13.75mm

COMPRESSION DATA

The force required to compress the diameter of the lens 0.5mm lesss than the original diameter.

PREOP VISUAL ACUITY	ECCE N=87	ECCE Secondary N=61	Posterior N=7	Back-up N=3	Overall 3 Year N=148
20/40 or Better	0.172g	0.198g			

The force required to compress the diameter of the lens 0.5mm lesss than the original diameter after lens has been compressed this distance for 24 hours at 37°C in de-ionized water.

PREOP VISUAL ACUITY	ECCE N=87	ECCE Secondary N=61	Posterior N=7	Back-up N=3	Overall 3 Year N=148
20/40 or Better	0.098g	0.106g			

The force required to compress the diameter of the lens the maximum amount expected in clinical usage after a 3 year implantation.

PREOP VISUAL ACUITY	ECCE N=87	ECCE Secondary N=61	Posterior N=7	Back-up N=3	Overall 3 Year N=148
20/40 or Better	0.172g	0.198g			

The force required to compress the diameter of the lens the maximum amount expected in clinical usage after lens has been compressed this distance for 24 hours at 37°C in de-ionized water.

PREOP VISUAL ACUITY	ECCE N=87	ECCE Secondary N=61	Posterior N=7	Back-up N=3	Overall 3 Year N=148
20/40 or Better	0.098g	0.106g			

VAULTING DATA

The vault observed after compressing the diameter 1mm beyond the maximum amount expected in clinical usage:

PREOP VISUAL ACUITY	ECCE N=87	ECCE Secondary N=61	Posterior N=7	Back-up N=3	Overall 3 Year N=148
20/40 or Better	0.143mm	vault with force of 0.630g at 10.00mm compressed diameter			
20/40 or Better	0.143mm	vault with force of 0.630g at 11.00mm compressed diameter			
20/40 or Better	0.599g at 11.00mm compressed diameter				

SIZING GUIDANCE

Recommended lens sizing (corneal diameter):

10.00mm to 11.49mm	12.50mm
11.50mm to 12.25mm	13.00mm

MODE OF ACTION

When implanted, the Bausch & Lomb Incorporated anterior chamber intraocular lens functions as a refracting medium to replace the natural lens in the visual correction of aphakia.

INDICATIONS

Lenses in the Bausch + Lomb Surgical Model 122UV series are intended to be used for the visual correction of aphakia with adult patients where a cataractous lens has been removed by one of the following:

- primary intracapsular cataract extraction;
- primary extracapsular cataract extraction;
- primary extracapsular cataract extraction when there is a structural reason where the anterior chamber lens would be the preferred one;
- prior surgery such that a secondary implantation is required.

CAUTION

Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition may interfere with treatment of a condition, or may pose an unreasonable risk to the patient's eyesight:

- congenital bilateral cataracts;
- recurrent anterior or posterior segment inflammation of unknown etiology;
- patients with eyes having foreshortened anterior segments, e.g., microphthalmos or certain forms of chronic angle-closure glaucoma;
- previous history of, or a predisposition to, retinal detachment;
- patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment disease;
- surgical difficulties at the time of cataract extraction which might increase the potential for complications, e.g., persistent bleeding, significant iris damage, inability to reconstruct the anterior chamber, or inability to achieve acceptable positive pressure, significant vitreous loss, or significant anterior chamber bleeding;
- only one eye with potentially good vision;
- medically uncontrolled glaucoma;
- corneal endothelial dystrophy;
- proliferative diabetic retinopathy.

NOTE

Implantation of intraocular lenses should not be performed in patients under the age of 18. (Contact Bausch & Lomb Incorporated for other pediatric implant options.)

WARNINGS

As with any surgical procedure there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: lens dislocation, corneal edema, corneal decompensation, non-pigment precipitates, cystoid macular edema, infection (endophthalmitis), retinal detachment, vitreous loss, pupillary block, secondary glaucoma, iritis, iridocyclitis, vitreous wick syndrome, uveitis and pupillary membrane.

Some aftercare medications which have been associated with the implantation of intraocular lenses are as follows: hypopyon, acute corneal decompensation, lens repositioning, lens removal due to corneal touch, lens removal due to inflammation, corneal transplant, intraocular infection, lens replacement, vitreous aspiration for pupillary block, infection for pupillary block.

The safety of intraocular lens implantation has not been substantiated in patients with the following conditions: severe diabetes, severe myopia, severe hypertension, severe arthritis, rheumatoid, previous corneal transplant, history of herpes simplex or herpes zoster, ophthalmic complications unrelated to the implant, patients should explore the use of alternative methods of aphakic correction in patients with these conditions. The use of alternative methods of aphakic correction should be explored in patients with these conditions. The long-term effects of implanting intraocular lenses in these conditions are not yet well determined. Therefore, physicians should continue to monitor implant patients postoperatively on a regular basis.

Physicians considering lens implantation in patients with senile macular or retinal degeneration should be aware that the patient may not achieve any improvement in central visual acuity following intraocular lens implantation.

Patients with ocular pathology, e.g., glaucoma or corneal diseases, may not achieve the visual acuity of patients without such problems.

Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be monitored postoperatively for 2 years.

Hyphema, secondary glaucoma, pupillary block, cystoid macular edema, retinal detachment, vitreous loss, and corneal edema have been reported at increased rates in patients who have experienced surgical complications associated with the cataract extraction procedure (posterior capsule rupture, detached Descemet's membrane, anterior chamber bleeding, and vitreous bulge or loss). Patients experiencing surgical difficulties who develop postoperative complications such as macular edema may not achieve as good a visual result as patients without these complications. Patients who have experienced complications should be monitored carefully postoperatively for the occurrence of these complications. The need for a secondary implantation or surgical iridectomy should be considered on a more indeterminate at time of intraocular lens implantation.

The effectiveness of UV-inhibiting intraocular lenses in reducing the incidence of retinal disorders has not been established.

Some Bausch & Lomb Incorporated intraocular lenses are manufactured with optics made of ultraviolet light absorbing material. Patients who have undergone cataract surgery with an intraocular lens having a narrow or small optic may result in the patient experiencing glare or other visual disturbances under certain conditions. Ophthalmic surgeons should consider this potential before implanting an intraocular lens with a small or narrow optic.

PRECAUTIONS

1. Do not sterilize. Lenses requiring resterilization should be returned to Bausch & Lomb Incorporated.
2. Do not store the lens in direct sunlight or at temperatures greater than 110° Fahrenheit.
3. Do not soak or rinse lenses in antibiotic solutions. Intraocular lenses can adsorb antibiotics.
4. A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed or assisted in numerous surgical implantations and should have completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.

MEDICAL DEVICE RE-USE STATEMENT

This product is intended for single use, disposable use-only. Bausch + Lomb cannot guarantee the functionality, material structure, or cleanliness or sterility of the product. Re-use could lead to illness, infection and/or injury to the patient or user, and, in extreme cases, patient death. This product is labelled as 'single use' which is defined as a device intended to be used once only for a single patient.

WARNING

- This lens is not intended, nor should it be used, for a clear lens exchange.
- Special consideration should be given to the dimensions of lenses at the extreme ends of the power range in relation to the anatomical dimensions in the patient's eye. The potential impact of factors such as optic central thickness, optic edge thickness and overall lens size on a patient's long-term corneal status should be carefully weighed against the potential benefit associated with the implantation of an intraocular lens. This is particularly true for anterior chamber lenses. The patient's clinical progress should be carefully monitored.

REPORTING

Adverse reactions and/or potentially sight threatening complications that may reasonably be regarded as lens related and have resulted in permanent impairment of vision to a major or degree of incidence should be reported within five (5) days to Bausch & Lomb Incorporated. This information will be used to help improve the product and instructions in order to document potential long-term effects of intraocular lens implantation.

- Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with intraocular lenses. These problems may be related to a specific lot or lots of lenses or may be indicative of long-term effects associated with these lenses or with IOLs in general.
- If the patient has a Bausch + Lomb intraocular lens and you wish to report, for U.S. residents please call:

Bausch & Lomb Incorporated
1-800-2000

For non U.S. residents please contact your distributor or Bausch + Lomb affiliate.

CALCULATION OF LENS POWER

- The physician should determine preoperatively the power of the intraocular lens to be implanted. Lens power calculation methods are described in the references listed in the bibliography at the end of this insert. Additional information on lens power calculation may also be available upon request.

HOW SUPPLIED

Bausch & Lomb Incorporated intraocular lenses are supplied STERILE in a dry heatsealed package. The inner package is thermally sterilized and should be opened only under sterile conditions (see section "Directions For Use").

EXPIRATION DATE

The expiration date on the lens package is the sterility expiration date. Any lens held after this date should be returned to Bausch & Lomb Incorporated. Lenses should not be used, or reused, Bausch & Lomb cannot guarantee the functionality, material structure or sterility of the product. Reuse could lead to infection or injury to the patient or user. This product is for single use and is intended to be used once only for a single patient.

WARRANTY

Bausch & Lomb Incorporated warrants that the intraocular lens, when delivered, will conform to all applicable laws and regulations of the manufacturer, and to the published specifications for such intraocular lens in all material reports and will be free from defects in material or workmanship.

BAUSCH & LOMB INCORPORATED DISCLAIMS ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL BAUSCH & LOMB INCORPORATED BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT OR EXEMPLARY DAMAGES OF ANY KIND, DIRECTLY, OR INDIRECTLY ARISING FROM THE PURCHASE OR USE OF THIS PRODUCT EVEN IF BAUSCH & LOMB INCORPORATED HAD BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, DAMAGE OR EXPENSE.

RETURN GOODS POLICY

Bausch & Lomb Incorporated direct purchased lenses may be returned for credit if unopened, in original packaging and within one year from the date of invoice, subject to approval and issuance of a Return Goods Authorization number prior to the return of the product. Lenses returned after the date of the invoice, or lenses opened or expired lenses, may be exchanged for another lens of similar design. Discontinued, special sale or no charge lenses may not be returned for credit or exchange. A Return Goods Authorization may be obtained by calling 1-800-338-2020.

DIRECTIONS FOR USE

- To remove the lens, peel open the outer bag and remove the tray in a sterile environment.
- Carefully lift the lid (clear tray) or slide the lid backward (gray tray) to expose the lens.
- Remove the lens by grasping the haptic, using smooth forceps, sterile cotton tipped applicators, locking forceps or needle holders should never be used.
- Do not scale or crease the lens or handle the lens other than balanced salt solutions or their equivalent.
- Note because the lens and the packaging materials are plastic, the lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.
- Bausch & Lomb Incorporated one-piece PMMA lenses are designed to compress in the plane of the lens only. To avoid damage to the haptic, do not attempt to compress, flex, fix haptics out of the plane of the lens or twist or torque the lens.
- Prior to implantation, rinse the lens for tope, power, proper configuration and optical surfaces.

PATIENT REGISTRATION INSTRUCTIONS

Bausch & Lomb Incorporated will continue a patient registration system in order to contact physicians if additional information regarding long-term effects of the lenses are discovered. The lens package contains product identification stickers for maintaining a record of lens usage and patient information. Following the date of surgery, the physician will record lens information on the stickers to fill out the patient registration card and return it to Bausch & Lomb Incorporated. Bausch & Lomb Incorporated will maintain a record of all intraocular lens implants for the purpose of contacting the patient if notification of these lenses. It is critical that registration be completed for all patients.

An implant identification card is to be supplied to the patient with the lens in the package. The patient should be instructed to keep the card as a permanent record of the implant. The patient should also be instructed to show the card to any eye practitioner he or she may see in the future.

CLINICAL EXPERIENCE

Bausch & Lomb Incorporated Model 121UV anterior chamber lenses were implanted in over 2,000 patients. The results achieved by the 218 case patients successfully followed for one year indicate that the Bausch & Lomb Incorporated Model 121UV anterior chamber lenses are safe and effective devices for the visual correction of aphakia.

PATIENT POPULATION

The patient population in the clinical trials consisted of 58.4% females and 37.4% males; (4.2% were unidentified). The average age was 74.0 years; minimum age, 22.2; were Black and 1.4% were described as "Other" (8.5% were not identified according to race). The mean age for the visual acuity study was 73 years.

VISUAL ACUITY

The following is a summary of final visual acuity (12+ months postoperative) achieved by Bausch & Lomb Incorporated Model 121UV anterior chamber lens implant patients:

BEST CASE PRIMARY IMPLANT PATIENTS

AGE DECADE	N	20/40 or Better	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	11	100	0	0	0	0
71-80 Yrs.	53	96	2	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	72	97	1	0	0	0
3 Yr.						

ALL SECONDARY IMPLANTS
VISUAL ACUITY 12+ MONTHS

AGE DECADE	N	20/40 or Better	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	11	100	0	0	0	0
71-80 Yrs.	53	96	2	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	72	97	1	0	0	0
3 Yr.						

ALL REPLACEMENT IMPLANTS

AGE DECADE	N	20/40 or Better	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	11	100	0	0	0	0
71-80 Yrs.	53	96	2	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	72	97	1	0	0	0
3 Yr.						

BEST CASE INTRACAPSULAR CATARACT EXTRACTION

AGE DECADE	N	< 20/40	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	11	100	0	0	0	0
71-80 Yrs.	31	100	0	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	50	100	0	0	0	0
3 Yr.						

BEST CASE EXTRACAPSULAR CATARACT EXTRACTION

AGE DECADE	N	< 20/40	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	11	100	0	0	0	0
71-80 Yrs.	31	97	3	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	50	97	2	0	0	0
3 Yr.						

CUMULATIVE INCIDENCE

	ECCE N=87	ECCE N=28	Secondary N=32	Posterior N=2	Back-up N=1	Overall 3 Year N=104
Cyclitic Membrane	2.4%	3.6%	0%	0%	0%	1.9%
Endophthalmitis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyphema	0.0%	0.0%	0.0%	0.0%	0.0%	4.8%
Iritis	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Upper Corneal Edema	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Lens Dislocation	2.4%	0.0%	3.1%	0.0%	0.0%	1.9%
Macular Edema	7.3%	0.0%	1.3%	50.0%	0.0%	4.8%
Pupillary Block	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Retinal Detachment	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Secondary Glaucoma	9.8%	0.0%	3.1%	50.0%	0.0%	5.8%
Vitritis	0.0%	3.6%	0.0%	0.0%	0.0%	0.0%

CUMULATIVE INCIDENCE

	ECCE N=87	ECCE N=28	Secondary N=32	Posterior N=2	Back-up N=1	Overall 3 Year N=104
Cyclitic Membrane	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Endophthalmitis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyphema	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Iritis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Upper Corneal Edema	0.0%	0.0%	0.0%	0.0%	0.0%	1.0%
Lens Dislocation	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Macular Edema	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pupillary Block	0.0%	0.0%	0.0%	0.0%	0.0%	1.0%
Retinal Detachment	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Secondary Glaucoma	0.0%	7.1%	0.0%	0.0%	100.0%	2.9%
Vitritis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

ADVERSE REACTIONS

	Overall 3 Year N=148
Hypopyon	0.0%
Intraocular Infection	0.0%
Acute Corneal Decompensation	0.3%
Secondary Surgical Intervention	0.3%
Repair Retinal Detachment	1.3%
Reposition Lens	0.0%
Resuture Corneal Graft	0.0%
Corneal Transplant	1.3%
Enucleation	0.0%

This addendum summarizes the clinical results achieved by Bausch & Lomb Incorporated Models 121 UV Anterior Chamber Lens implants successfully followed for three years.

BEST CASE
PRIMARY IMPLANT PATIENTS

AGE DECADE	N	< 20/40	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	18	100	0	0	0	0
71-80 Yrs.	31	97	3	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	57	97	2	0	0	0
3 Yr.						

ALL SECONDARY IMPLANTS

AGE DECADE	N	< 20/40	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	18	100	0	0	0	0
71-80 Yrs.	31	97	3	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	57	97	2	0	0	0
3 Yr.						

ALL REPLACEMENT IMPLANTS

AGE DECADE	N	< 20/40	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	18	100	0	0	0	0
71-80 Yrs.	31	97	3	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	57	97	2	0	0	0
3 Yr.						

BEST CASE INTRACAPSULAR CATARACT EXTRACTION*

AGE DECADE	N	< 20/40	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	18	100	0	0	0	0
71-80 Yrs.	31	97	3	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	57	97	2	0	0	0
3 Yr.						

BEST CASE EXTRACAPSULAR CATARACT EXTRACTION*

AGE DECADE	N	< 20/40	20/41-20/80	20/81-20/100	20/101-20/200	> 20/200
< 60 Yrs.	0	0	0	0	0	0
61-70 Yrs.	18	100	0	0	0	0
71-80 Yrs.	31	97	3	0	0	0
> 80 Yrs.	8	100	0	0	0	0
OVERALL	57	97	2	0	0	0
3 Yr.						

* Patients with macular degeneration or pre-existing pathology have been excluded.

COMPLICATIONS

The U.S. Food and Drug Administration has identified, as potentially sight-threatening, twelve (12) complications which may occur following cataract extraction and/or intraocular lens implantation. The occurrence rates of these complications during the first year following surgery for Bausch & Lomb Incorporated Model 121UV anterior chamber intraocular lens implants are as follows:

CUMULATIVE INCIDENCE

	ECCE N=87	ECCE N=61	Secondary N=61	Posterior N=7	Back-up N=3	Overall 1 Year N=148
Cyclitic Membrane	2.4%	3.6%	0%	0%	0%	1.9%
Endophthalmitis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyphema	0.0%	0.0%	0.0%	0.0%	0.0%	4.8%
Iritis	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Upper Corneal Edema	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Lens Dislocation	2.4%	0.0%	3.1%	0.0%	0.0%	1.9%
Macular Edema	7.3%	0.0%	1.3%	50.0%	0.0%	4.8%
Pupillary Block	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Retinal Detachment	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Secondary Glaucoma	9.8%	0.0%	3.1%	50.0%	0.0%	5.8%
Vitritis	0.0%	3.6%	0.0%	0.0%	0.0%	0.0%

CUMULATIVE INCIDENCE

	ECCE N=87	ECCE N=61	Secondary N=61	Posterior N=7	Back-up N=3	Overall 1 Year N=148
Cyclitic Membrane	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Endophthalmitis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyphema	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Iritis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Upper Corneal Edema	2.4%	0.0%	0.0%	0.0%	0.0%	1.0%
Lens Dislocation	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Macular Edema	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pupillary Block	0.0%	0.0%	0.0%	0.0%	0.0%	1.0%
Retinal Detachment	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Secondary Glaucoma	0.0%	7.1%	0.0%	0.0%	100.0%	2.9%
Vitritis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Listed below are the most common adverse events and adjunct trials of Bausch & Lomb Incorporated Model 121UV as of December 1, 1985.

	Core N=315	Adjunct N=95
Hypopyon	0	0.10%
Intraocular Infection	0	0.10%
Acute Corneal Decompensation	0.63%	0.07%
Secondary Surgical Intervention		
Lens Repositioned with or without replacement	1.92%	0.00%
Lens Repositioning	0.32%	0.00%
Repair Detached Retina	0.32%	0.00%
Corneal Graft	0.95%	0.00%
Corneal Transplant	0.95%	0.02%
Enucleation	0.00%	0.00%

BIBLIOGRAPHY

General

Apple, D.J., et al. "Evolution of intraocular lenses." Ophthalmology, 1985, 1-23.
Boettner, E.A. and Wolter, J.R. "Transmission of the ocular media." Invest. Ophthal., 1962, 776-783.
Hoffer, K.J. "Biometry of the eye." CLAO Journal, 1983, 9(1), 15-19.
Jaffe, N.S. "Suspended lenses for intraocular lens implant surgery." Archives of Ophthalmology, 1977, 94, 214-216.
Jaffe, N.S. "The way lenses were and are: changing indications for intraocular lens implantation." Ophthalmology, 1983, 90(4), 318-320.
Jaffe, N.S. "The current status of intraocular lenses." Geriatric Ophthalmology, 1985, 37-46.
McDonnell, P.J., Green, W.R. "Pathology of intraocular lens in 33 eyes examined postmortem." Ophthalmology, 1985, 92(4), 386-400.
Ridley, Harold. "The origin and objectives of intraocular lenticular implants." American Academy of Ophthalmology and Otolaryngology. Transactions, 1976, 8, 64-66.
Symposium: Intraocular Lenses.
Shepard, Dennis D. The Intraocular Lens Manual. Santa Marla, CA: Shepard Inc., 1982.

Anterior Chamber Lenses

Boerner, C.F., Thrasher, J., B.H. "Complications from Anterior Chamber Lenses: Report of Large Series." Ophthalmic Surgery, 16:8, 742-4, August 1984.
Choyce, D.P. "The Latest Facts and Figures on Anterior Chamber Lens Implants." Read Before Royal Soc. of Medicine in Bristol/May 13, 1976.
Fedorov, A.G. et al. "Morphologic Characteristics of Flexible Loop Anterior Chamber Intraocular Lenses." Archives of Ophthalmology, 101:9, 1429-33 September 1983.
Hagan, 3rd, J.C. "A Comparative Study of the 912 and Other Anterior Chamber Intraocular Lenses." Journal of the American Intraocular Implant Society, 10:3, 324-8, Summer 1984.
Kraff, M.C., Sanders, D.R., Lieberman, H.L. "300 Primary Anterior Chamber Lens Implantations: Results of Primary and Secondary Implants Using Choice Mark VIII Lenses." Archives of Ophthalmology, 101:9, 1429-33 September 1983.
Tennant, J.L. "Results of Primary and Secondary Implants Using Choice Mark VIII Lenses." Ophthalmic Surgery, Vol. 8, No. 3, 54-56, June 1977.
Sanders, D.R., Kraff, M.C. "Improvement of intraocular lens power using empirical data." American Intraocular Implant Society Journal, 1980, 6(2).
Plexiglas® UF3 is a registered trademark of Rohm and Haas Company, Philadelphia, PA, USA

BAUSCH + LOMB
Bausch & Lomb Incorporated
Scientific Products Division
One Lomb Place
Rochester, NY 14609 USA

EC REP
Bausch & Lomb GmbH
Bausch & Lomb Allee 1
Postfach 1246
63801 Kleinostheim Germany

STERILE EO

Manufacturing site: Bausch & Lomb Incorporated
21 Park Place Blvd. North
Clearwater, FL 33759 USA
© 2015 Bausch & Lomb Incorporated. All rights reserved.

Rev. 2018-08

FR

Pour ceux qui n'habitent pas aux E.U. veuillez contacter votre distributeur ou une filiale Bausch & Lomb.

CALCUL DE PUISSANCE DE L'OPTIQUE

Le médecin doit déterminer avant l'opération la puissance de la lentille intraoculaire qui sera implantée. Des méthodes de calcul de puissance de lentille sont décrites dans les références énumérées dans la bibliographie à la fin de cet encart. De même, les médecins peuvent demander des informations supplémentaires sur le calcul de puissance de lentille peuvent entrer en contact avec Bausch & Lomb Incorporated, Clearwater, Floride.

MODE D'ACTION

Les lentilles intraoculaires Bausch & Lomb Incorporated sont livrées STERILES dans un emballage hermétique. Le conditionnement intérieur est thermostérilisé et ne doit être ouvert que dans des conditions stériles (voir la section "mode d'emploi").

LIMITE D'UTILISATION

La date limite d'utilisation sur l'emballage de la lentille est la date limite de stérilité. Toutes lentilles conservées au-delà de cette date doivent être retournées à Bausch & Lomb Incorporated. En cas de retraitement ou de réutilisation, Bausch & Lomb ne peut garantir ni bon fonctionnement, la structure matérielle ou la stérilité du produit. La réutilisation peut occasionner au patient ou à l'utilisateur une infection ou une blessure. Ce produit est à usage unique et est conçu pour être utilisé une seule et unique fois pour un seul et unique patient.

CHANGEMENTS

Bausch & Lomb Incorporated garantit que la lentille intraoculaire, lorsqu'elle est livrée, est conforme à toutes les lois et réglementations applicables du fabricant et à toutes les spécifications concernant les spécifications de la lentille intraoculaire en question publiées dans tous les rapports de matériaux et publications techniques. Bausch & Lomb Incorporated DÉCLINE TOUTES AUTRES GARANTIES, EXPRESSES, IMPLICITES OU LÉGALES, Y COMPRIS, MAIS SANS LIMITATION, TOUTE GARANTIE IMPLICITE DE VALEUR MARCHANDE OU D'APTITUDE À UN BUT PARTICULIER. BAUSCH & LOMB INCORPORATED NE SERA PAS TENU POUR RESPONSABLE DES DOMMAGES-INTÉRÊTS EXCEPTIONNELS, DES DOMMAGES-INTÉRÊTS EXEMPLAIRES DE QUELLE QUE SORTE QUE CE SOIT, DOMMAGES DIRECTS/INDIRECTS OU DÉPENSES DE QUELLE QUE SORTE QUE CE SOIT, DE CE PRODUIT MÊME SI BAUSCH & LOMB INCORPORATED AVAIT ÉTÉ AVERTI DE LA POSSIBILITÉ D'UNE TELLE PERTE, DOMMAGE OU DÉPENSE.

POLITIQUE DE RETOUR DE MARCHANDISES

Les produits Bausch & Lomb Incorporated achetés directement à Bausch & Lomb Incorporated peuvent être renvoyés pour remboursement dans l'emballage d'origine, si non ouverts, dans les 60 jours à partir de la date de facture, sous réserve d'approbation et d'émission d'un numéro d' **Autorisation de retour de marchandises** avant le retour du produit.Les lentilles endommagées ou périmées ne peuvent pas être retournées. Les lentilles périmées ne peuvent être échangées que contre une autre lentille de conception semblable. Les lentilles dont la date d'expiration est dépassée ou les lentilles de type spécial ne sont pas éligibles pour un remboursement ou un remplacement. Les lentilles spéciales ou les lentilles gratuites ne peuvent être ni remboursées ni échangées. Il est nécessaire de contacter Bausch & Lomb Incorporated pour obtenir un numéro d'autorisation de retour de marchandises en appelant le 1-800-325-9500.

MODE D'EMPLOI

- Pour retirer la lentille, ouvrez le sac externe en tirant sur la languette et retirez le plateau dans un environnement stérile.
- Soulevez soigneusement le couvercle (plateau clair) ou faites glisser le couvercle vers l'arrière (plateau gris) pour exposer la lentille.
- Enlevez la lentille en saisissant l'optique, au moyen de forceps à bord lisse, et en la soulevant du plateau. Ne jamais utiliser de pince à dents ou de porte-aiguille.
- Ne touchez ou ne manipulez la lentille dans une solution autre que saline équilibrée ou équivalente.
- **Remarque :** Puisque la lentille et les matériaux de conditionnement sont en plastique, il est possible que la lentille reçoive une charge électrostatique lors de l'ouverture de l'emballage. La lentille doit être soigneusement examinée afin de s'assurer qu'elle n

Bausch & Lomb Incopyand
1-(800) 338-2020

Para residentes de fora dos Estados Unidos, por favor, contatate seu distribuidor local antes de utilizar Bausch & Lomb.

CÁLCULO DA POTÊNCIA DA LENTE
Antes da operação, é preciso determinar a potência da lente intra-ocular a ser implantada. Os métodos de cálculo da potência da lente encontram-se descritos nas referências bibliográficas fornecidas. Entretanto, os médicos devem decidir, em cada caso, quais os dados e os métodos de cálculo da potência das lentes podem contribuir a melhores resultados pós-operatórios. Bausch & Lomb Incorporated, Clearwater, FL 33759.

APRESENTAÇÃO
As lentes intra-oculares da Bausch & Lomb Incorporated são fornecidas ESTÉREIS numa embalagem selada por calor seco. A embalagem interior é esterilizada após o processo de embalagem e deve ser aberta unicamente em condições estéreis (consultação secção "Instruções de utilização").

DATA DE VALIDADE
A data de validade ou embalagem das lentes é a data de validade da esterilidade. Caso ocorra uma lente com data de validade ultrapassada, contate o Bausch & Lomb Incorporated, Clearwater, FL 33759. Se este produto for reprocessado ou reutilizado, a Bausch & Lomb não pode garantir a funcionalidade ou esterilidade do dispositivo do produto. A reutilização poderá causar infecções ou lesões no paciente ou utilizador. Este produto é para utilização única e destina-se a ser utilizado uma única vez por um único paciente.

GARANTIA
A Bausch & Lomb Incorporated garante que a lente intra-ocular, no momento em que é entregue, está conforme à legislação, regulamentos e especificações do fabricante aplicáveis publicadas pelo fabricante para a referida lente em todos os aspectos materiais e que estará livre de defeitos de fabrico material ou na fabricação.
A BAUSCH & LOMB INCORPORATED EXCLUI QUAISQUER OUTRAS GARANTIAS, SEJAM ELAS EXPRESSAS, IMPLÍCITAS, ESTATUTÁRIAS OU APLICÁVEIS POR LEI OUTRAS, INCLUSIVE ENTRE OUTRAS, QUAISQUER GARANTIAS IMPLÍCITAS DE COMERCIABILIDADE OU ADEQUAÇÃO PARA UM DETERMINADO FIM. A BAUSCH & LOMB INCORPORATED NÃO SOB NENHUMA CIRCUNSTÂNCIA É RESPONSÁVEL POR DANOS ACIDENTAIS, INDIRETOS, EXEMPLARES OU QUALQUER NATUREZA, DIRETOS OU INDIRETAMENTE PROVOCADO PELA COMPRA OU UTILIZAÇÃO DESTE PRODUTO. BAUSCH & LOMB INCORPORATED TENDA SIDO AVISADA DA POSSIBILIDADE DE TAL PERDA, DANO OU DESPESA.

POLÍTICA DE DEVOLUÇÃO DE PRODUTOS
As lentes descartáveis comprendidas na Bausch & Lomb Incorporated podem ser devolvidas para crédito caso não estejam danifas, na embalagem original, nos 60 dias após a data de facturação, dependendo do período de validade restante. **Não aceitamos devoluções de devolução** de produtos. antes da devolução do produto. As lentes devolvidas 60 dias depois da data de facturação ou as lentes com o prazo de validade expirado, podem ser trocadas apenas por outra lente de tipo similar. As lentes cujo fabrico foi suspendido, por um forte comprometido por preços especiais ou lentes especiais não podem ser devolvidas para crédito ou troca. Poderá obter uma **autorização de devolução de produtos** telefonando para o 1-800-338-2020.

INSTRUÇÕES DE UTILIZAÇÃO
- Para retirar a lente, abra o saco externo e retire o tabuleiro num ambiente estéril.
- Levante cuidadosamente a cobertura (tabuleiro transparente) ou faça destacar a cobertura, para trás (tabuleiro colorido) para expor a lente.
- Retire a lente, agarrando a óptica, utilizando uma pinça de pontas macias e levantando.
- Nunca deverá ser usada pinça com bordas serrilhadas ou rugosas.
- Não embeba nem enxague a lente em soluções que não sejam as soluções salinas equilibradas ou equivalentes.
- **Nota:** Sendo a lente e o material de embalagem plásticos, a lente pode adquirir uma carga electrostática quando é retirada do tabuleiro. Isto é normal e não deve ser considerado, examinada para se ter a certeza de que nenhuma partícula é atraída para a lente. Se for necessário, a carga estática pode ser removida da lente com humedecimento com um pano ou esponja. Para evitar ingestões, não lente enquanto estiver hipóxicos, fisiologicamente hipóxicos fora do plano da lente ou deformar ou torcer a lente.
- Antes da implantação, examine a lente quanto ao tipo, potência, configuração adequada e superfícies ópticas.

INSTRUÇÕES PARA O CUIDADO DE PACIENTES
A Bausch & Lomb Incorporated continuará a estabelecer um sistema de registo de pacientes de forma a contactar pacientes e médicos quando necessário. Pedimos a longo prazo das lentes ainda não reconhecidos. A embalagem da lente contém rótulos adesivos para a monitorização do paciente e um cartão de registo do paciente. No momento da circunção, o cartão de registo de implante pré-pago incluído na embalagem deve ser preenchido e enviado. Para a Bausch & Lomb, Incorporated, Clearwater, FL 33759. Bausch & Lomb Incorporated irá manter um registo de todos os implantes de lentes intra-oculares para monitorizar qualquer problema a longo prazo associado a implantação desses lentes. É essencial que o registo seja preenchido para todos os pacientes.

A embalagem contém ainda um cartão de identificação do implante a ser fornecido ao paciente. Os pacientes devem ser aconselhados a manter o cartão de registo permanente do seu implante. O paciente deve também ser instruído no sentido de apresentar o cartão a qualquer médico oftalmologista que o examine.

EXPERIÊNCIA CLÍNICA
Os resultados clínicos das lentes da câmara anterior do modelo 122UV da Bausch & Lomb Incorporated foram iniciados em Março de 1985 pela Storz Ophthalmics, Inc. Os resultados alcançados pelos 218 pacientes do grupo central acompanhados no período de dois durante um ano indicam que as lentes da câmara anterior do modelo 122UV da Bausch & Lomb Incorporated foram bem aceites para a correcção da afacia.

POPULAÇÃO DE PACIENTES
A população nos ensaios clínicos era constituída por 64% de mulheres e 37.4% homens (4.2% não foram identificados quanto ao sexo); 69.7% eram de raça caucasiana; 22.2% eram de raça negra e 1.4% Hispânicos; 2.8% pertenciam a outras raças e 3.9% não indicaram quanto a raça). A idade média para essa população era de 73 anos.

AVISO ADICIONAL
Pode ser consultado na secção em inglês um resumo da acuidade visual final (12+ meses pós-cirúrgico) relativamente aos pacientes que receberam os implantes de lentes da câmara anterior modelo 121 UV da Bausch & Lomb Incorporated.

	Geral 3 anos Nº
Hipópio	0,0%
Infecção intra-ocular	0,0%
Descompensação corneal aguda	0,0%
Hemorragia intraocular aguda	0,0%
Deslocamento de reparação retinal	2,9%
Glaucoma pós-cirúrgico	1,9%
Resistura de enxerto corneal	1,0%
Transplante de córnea	1,9%
Vitrectomia	1,0%

REFERÊNCIAS
Gerard
Apple, D.J., et al. "Evolution of intraocular lenses." Ophthalmology, 1985, 1-23
Boettner, E.A. and Wolter, J.R. "Transmission of the ocular media." Invest. Ophthal., 1962, 1: 776-783-curve #2 of Figure 5.
Holladay, J.T., et al. "The ideal intraocular lens." CLAO Journal, 1983, 9(1), 15-19.
Jaffe, N.S. "Suggested guidelines for intraocular lens implant surgery." Archives of Ophthalmology 1977, 94, 214-216.
Jaffe, N.S. "The way things were and are: changing indications for intraocular lens implantation." Ophthalmology, 1983, 90(4), 338-350.
Jaffe, N.S. "The current status of intraocular lenses." Geriatric Ophthalmology, 1985, 37-46.
McDonnell, P.J., Green, W.R. "Pathology of intraocular lens in 33 eyes examined postmortem." Ophthalmology, 1983, 90(4), 398-402.
Hilbig, Harold. "The origin and objectives of intraocular lenticular implants." American Academy of Ophthalmology an Otolaryngology. Transactions, 1976, 8, 65-66.
Symposium: Intraocular Lenses.
Choyce, D.P. "The Lancaster Lens." Medical Lens Manual. Santa Maria, CA: Shepard Inc., 1982.
Lentes da câmara anterior
Boerner, C.F., Thrasher, Jr., B.H. "Complications from Anterior Chamber Lenses: Report of Cases." Archives of Ophthalmology, 93, 1-4, January 1975.
Choyce, D.P. "The Elliot Facts and Figures on Anterior Chamber Lens Implants." Read Before Royal Soc. of Medicine in Biotoc/May 13, 1976.
Duffin, R.M., Olson R.J. "Vaulting Characteristics of Flexible Loop Anterior Chamber Intraocular Lenses." Archives of Ophthalmology, 98, 1429-33 September 1980.
Hagan, 3rd, J.C. "A Comparative Study of the 9/12 and Other Anterior Chamber Intraocular Lenses." Journal of the American Intraocular Implant Society, 10, 3, 324-8, Summer 1984.
Kraff, M.C., Sanders, D.R., Lieberman, H.L. "300 Primary Anterior Chamber Lens Implantations" Gynecologic Findings and Gynecologic Microscopy." Journal of the American Intraocular Implant Society, 5, 207-D, July 1979.
Sakz, J.I., Jones, C.L. "234 Anterior Chamber Implants. Visual Results, Complications and Gonioscopy." Transactions of the American Intraocular Implant Society, 10, 3, 324-8, Summer 1984.
Shammas, H.K., Milikie, C.F. "Primary vs. Secondary Insertion of Anterior Chamber Lenses." Journal of the American Intraocular Implant Society, 5, 2, 141-2, April 1979.
Tennant, J.L. "Results of Primary and Secondary Implants Using Choyce Mark VIII Lenses." Ophthalmic Surgery, Vol. 8, No. 3, 54-56, June 1977.
Glaucoma pós-cirúrgico
Binkhorst, R.D. Intraocular Lens Power Calculation Manual. New York: Richard D. Binkhorst, 1979.
Donzis, P.B., et al. "An intraocular lens formula for short, normal and long eyes." CLAO Journal, 1985, 11(2), 96-98.
Gills, J.P. "Minimizing postoperative refractive errors." Contact Lens, 1980, 6(1), 56-59.
Hoffer, K.J. "Improving the predictability of intraocular lens power calculations." Ophthalmology, 1984, 91(1), 52-55.
Holladay, J.T., et al. "Improving the predictability of intraocular lens power calculations." Arch. Ophthalmology, 1986, 104, 539-541.
Jiang, Y., et al. "Analysis of intraocular lens power calculation." American Intraocular Implant Society Journal, 1985, 11, 268-271.
Retzlaff, J. "A new intraocular lens calculation formula." American Intraocular Implant Society Journal, 1985, 11, 153-158.
Sanders, D.R., Kraff, M.C. "Improvement of intraocular lens power using empirical data." American Intraocular Implant Society Journal, 1980, 6(2).

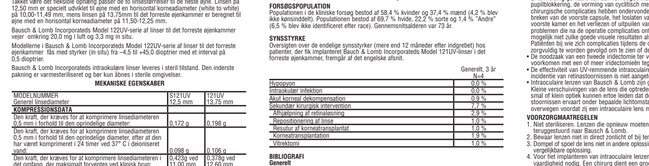
©2003 Bausch & Lomb Incorporated Alle rettigheder forbehdes.

Bausch & Lomb Model 122UV
Intraocular lenses til fortrese øjenkamer

DA

PRODUKTOPLYSNINGER
Læsning! Læsning omhyggelig hvis ord dette produkt kun sælges af eller på recept fra en læge.

BESKRIVELSE AF ENHEDEN
Bausch & Lomb Incorporated's Model 122UV-serie af intraokulære linser til det forreste øjenkamer, der produceres af Bausch & Lomb Incorporated, bestå af optiske komponenter til erstatning af naturlige øjenlinser, der er blevet fjernet som del af kirurgisk afslag. Linsernes udskæres (på en dreibænk) af Plexiglas® UF-3, et polymethylmethacrylat (PMMA) blødt UV-absorberende stof. Specifikke oplysninger om bestemte modeller udleveres efter behov. Alle øvrige oplysninger på denne indlægsseddel er gældende for alle modeller i Bausch & Lomb Incorporated's Model 122UV-serie af intraokulære linser til forreste øjenkamer. Linsernes disptriske styrke opbæres i en vandig opløsning. Linsen har et rettlinedesign på 1,4 mm, et overall diameter på 1,19 og en transmission af synlige lys på 90 % eller derover. Belgetlængden for skæringspunktet på 10 % transmission for UV-lys er 370 nm for modellerne på 4.0 og 380 nm for modellerne på +34.0. Bausch & Lomb Incorporated's Model 122UV-serie af intraokulære linser til forreste øjenkammer er lille og omfatter en fleksibel bøjle, der er fremstillet af en hvidfarvet polypropylen-monofilament, der har fået forstærket enden intraocular-lukkende kataraktekstraktion.



Tykket vare det fleksible ophæng passer de to linsestørrelser til de fleste øjne. Linsen på 12.50 mm er specielt udviklet til øjne med en horisontal kornediameter (white to white) på 10.00-11.8 mm, mens linsen på 13.75 mm er det forreste kamrum af en normal øje med en horisontal kornediameter på 11.50-12.25 mm.
Bausch & Lomb Incorporated's Model 122UV-serie af intraokulære linser til forreste øjenkammer tejer -orinking 20.0 mg i luft og 3,3 mg in situ.
Modellerne i Bausch & Lomb Incorporated's Model 122UV-serie af linser til det forreste øjenkammer fås med styrker (in situ) fra –4,5 til +45,0 dioptrier med et interval på 1,0 dioptrier.

Bausch & Lomb Incorporated's intraokulære linser leveres i steril tilstand. Den indeterte pakning er varmesterilisert og den kan åbnes i kirurgisk.

MEKANISKE EGENSKABER

MODELNUMMER	512UV	121UV
Overall linsediameter	12,5 mm	13,75 mm
KOMPRESSIONSDATA		
Den kraft, der kræves for at komprimere linsediameteren 0,5 mm i forhold til den oprindelige diameter.	0,172 g.	0,198 g.
Modellerne i Bausch & Lomb Incorporated's Model 122UV-serie af intraokulære linser til det forreste øjenkammer fås med styrker (in situ) fra –4,5 til +45,0 dioptrier med et interval på 1,0 dioptrier.
Bausch & Lomb Incorporated's intraokulære linser leveres i steril tilstand. Den indeterte pakning er varmesterilisert og den kan åbnes i kirurgisk.

MEKANISKE EGENSKABER

MODELNUMMER	512UV	121UV
Overall linsediameter	12,5 mm	13,75 mm
KOMPRESSIONSDATA		
Den kraft, der kræves for at komprimere linsediameteren 0,5 mm i forhold til den oprindelige diameter.	0,172 g.	0,198 g.
Den kraft, der kræves for at komprimere linsediameteren i det omfang, der maksimalt forventes ved klinisk brug.	0,199 g ved 12,00 mm	0,201 g ved 13,75 mm
Den kraft, der kræves for at komprimere linsediameteren i det omfang, der maksimalt forventes ved klinisk brug.	0,199 g ved 12,00 mm	0,201 g ved 13,75 mm
Den kraft, der kræves for at komprimere linsediameteren i det omfang, der maksimalt forventes ved klinisk brug.	0,199 g ved 12,00 mm	0,201 g ved 13,75 mm

BILLOGRAFI
Gennemt
Apple, D.J., et al. "Evolution of intraocular lenses." Ophthalmology, 1985, 1-23
Boettner, E.A. and Wolter, J.R. "Transmission of the ocular media." Invest. Ophthal., 1962, 1: 776-783-curve #2 of Figure 5.
Holladay, J.T., et al. "The ideal intraocular lens." CLAO Journal, 1983, 9(1), 15-19.
Jaffe, N.S. "Suggested guidelines for intraocular lens implant surgery." Archives of Ophthalmology 1977, 94, 214-216.
Jaffe, N.S. "The way things were and are: changing indications for intraocular lens implantation." Ophthalmology, 1983, 90(4), 338-350.
Jaffe, N.S. "The current status of intraocular lenses." Geriatric Ophthalmology, 1985, 37-46.
McDonnell, P.J., Green, W.R. "Pathology of intraocular lens in 33 eyes examined postmortem." Ophthalmology, 1983, 90(4), 398-402.
Hilbig, Harold. "The origin and objectives of intraocular lenticular implants." American Academy of Ophthalmology an Otolaryngology. Transactions, 1976, 8, 65-66.
Symposium: Intraocular Lenses.
Choyce, D.P. "The Lancaster Lens." Medical Lens Manual. Santa Maria, CA: Shepard Inc., 1982.
Lentes da câmara anterior
Boerner, C.F., Thrasher, Jr., B.H. "Complications from Anterior Chamber Lenses: Report of Cases." Archives of Ophthalmology, 93, 1-4, January 1975.
Choyce, D.P. "The Elliot Facts and Figures on Anterior Chamber Lens Implants." Read Before Royal Soc. of Medicine in Biotoc/May 13, 1976.
Duffin, R.M., Olson R.J. "Vaulting Characteristics of Flexible Loop Anterior Chamber Intraocular Lenses." Archives of Ophthalmology, 98, 1429-33 September 1980.
Hagan, 3rd, J.C. "A Comparative Study of the 9/12 and Other Anterior Chamber Intraocular Lenses." Journal of the American Intraocular Implant Society, 10, 3, 324-8, Summer 1984.
Kraff, M.C., Sanders, D.R., Lieberman, H.L. "300 Primary Anterior Chamber Lens Implantations" Gynecologic Findings and Gynecologic Microscopy." Journal of the American Intraocular Implant Society, 5, 207-D, July 1979.
Sakz, J.I., Jones, C.L. "234 Anterior Chamber Implants. Visual Results, Complications and Gonioscopy." Transactions of the American Intraocular Implant Society, 10, 3, 324-8, Summer 1984.
Shammas, H.K., Milikie, C.F. "Primary vs. Secondary Insertion of Anterior Chamber Lenses." Journal of the American Intraocular Implant Society, 5, 2, 141-2, April 1979.
Tennant, J.L. "Results of Primary and Secondary Implants Using Choyce Mark VIII Lenses." Ophthalmic Surgery, Vol. 8, No. 3, 54-56, June 1977.
Glaucoma pós-cirúrgico
Binkhorst, R.D. Intraocular Lens Power Calculation Manual. New York: Richard D. Binkhorst, 1979.
Donzis, P.B., et al. "An intraocular lens formula for short, normal and long eyes." CLAO Journal, 1985, 11(2), 96-98.
Gills, J.P. "Minimizing postoperative refractive errors." Contact Lens, 1980, 6(1), 56-59.
Hoffer, K.J. "Improving the predictability of intraocular lens power calculations." Arch. Ophthalmology, 1984, 91(1), 52-55.
Holladay, J.T., et al. "Improving the predictability of intraocular lens power calculations." Arch. Ophthalmology, 1986, 104, 539-541.
Jiang, Y., et al. "Analysis of intraocular lens power calculation." American Intraocular Implant Society Journal, 1985, 11, 268-271.
Retzlaff, J. "A new intraocular lens calculation formula." American Intraocular Implant Society Journal, 1985, 11, 153-158.
Sanders, D.R., Kraff, M.C. "Improvement of intraocular lens power using empirical data." American Intraocular Implant Society Journal, 1980, 6(2).

©2003 Bausch & Lomb Incorporated Alle rettigheder forbehdes.

Bausch & Lomb Model 122UV
Intraocular lenses til forreste øjenkammer

SV

PRODUKTBESKRIVNINGAR
Läs noga! Läs noga om denna produkt endast säljas av eller på recept av en läkare.

BESKRIVNING AV ENHETEN
Bausch & Lomb Incorporated's Modell 122UV-serie av intraokulära linser för det forreste ögonkammer, som producerats av Bausch & Lomb Incorporated, bestå av optiska komponenter till ersättning av naturliga ögonlinser som avlägsnats som del av kirurgisk ingrepp. Linserna utskärmas (på en dreibänk) av Plexiglas® UF-3, et polymethylmethacrylat (PMMA) blåtint UV-absorberande stoff. Specifikna uppgifter om bestemte modeller utlevereres efter behov. Alla övriga uppgifningar på denne indlægsseddel er gældende for alle modeller i Bausch & Lomb Incorporated's Model 122UV-serie af intraokulære linser til forreste øjenkammer. Linsernes disptriske styrke opbæres i en vandig opløsning. Linsen har et rettlinedesign på 1,4 mm, et overall diameter på 1,19 og en transmission af synlige lys på 90 % eller derover. Belgetlængden for skæringspunktet på 10 % transmission for UV-lys er 370 nm for modellerne på 4.0 og 380 nm for modellerne på +34.0. Bausch & Lomb Incorporated's Model 122UV-serie af intraokulære linser til forreste øjenkammer er lille og omfatter en fleksibel bøjle, der er fremstillet af et hvidfarvet polypropylen-monofilament, der har fået forstærket enden intraocular-lukkende kataraktekstraktion.

De intraoculäre Bausch & Lomb-linser av den Model 122UV-serie, modell 512UV i L1122UV, er en klein transparant hulprodukt det bestaat uit en biconvexe optische lens, die is bevestigd met de kunstpoot in de voorste oogkamer na een intra- of extracapsulaire cataractextractie.

Dankzij de flexibele hapticbeel dienen twee lengtematen in de meeste oogen. Meer informatie over de lengtematen is beschikbaar voor oogen met een horizontale corneadiameter van 11,9 mm tot 11,8 mm, en de versie van 13,75 mm voor voorste-kamerwijdten van 11,5 tot 12,25 mm.

De intraoculaire Bausch & Lomb-lens voor de voorste kamer, model 122UV, weegt droogweg 20 mg in lucht en 3,3 mg in situ.

De 122UV-modellen van de intraoculaire Bausch & Lomb-lenzen voor de voorste kamer zijn beschikbaar in sterkten (in situ) van –4,5 tot +45,0 dioptrie met tussenstappen van 1,5 dioptrie.

De intraoculaire Bausch & Lomb-lenzen worden steriel geleverd. Het binnenste pakket is gesteriliseerd na het verpakken en mag uitsluitend in een sterile omgeving worden geopend.

MECHANISCHE EIGENSCHAPPEN

MODELNUMMER	512UV	121UV
Overall lensdiameter	12,5 mm	13,75 mm
COMPRESSIEGEGEVENS		
De kracht die nodig is om de diameter van de lens tot 0,5 mm minder dan de oorspronkelijke diameter samen te drukken.	0,172 g.	0,198 g.
De kracht die nodig is om de diameter van de lens tot 0,5 mm minder dan de oorspronkelijke diameter samen te drukken na zo ver te zijn samengedrukt gedurende 24 uur bij 37°C in gebruiksgeschikt water.	0,199 g bij 12,00 mm	0,201 g bij 12,00 mm
De kracht die nodig is om de diameter van de lens maximaal samen te drukken is naar verwachting bij klinisch gebruik.	0,199 g bij 12,00 mm	0,201 g bij 12,00 mm
De kracht die nodig is om de diameter van de lens maximaal samen te drukken is naar verwachting bij klinisch gebruik.	0,199 g bij 12,00 mm	0,201 g bij 12,00 mm
Lensposition for gebruiksgeschikt water	10,00 mm	11,50 mm
Lensposition for gebruiksgeschikt water	10,00 mm	11,50 mm

GEZICHTSSCHERPTE
Het overzicht van de uiteindelijke gezichtsscherpte (12 maanden of langer na de operatie) van de patiënten met de intraoculaire Bausch & Lomb-lenzen voor de voorste kamer model 121 UV werden gegeven, is te vinden in de secte Pregis.

BIBLIOGRAFIE
Algemeen
Apple, D.J., et al. "Evolution of intraocular lenses." Ophthalmology, 1985, 1-23
Boettner, E.A. and Wolter, J.R. "Transmission of the ocular media." Invest. Ophthal., 1962, 1: 776-783-curve #2 of Figure 5.
Holladay, J.T., et al. "The ideal intraocular lens." CLAO Journal, 1983, 9(1), 15-19.
Jaffe, N.S. "Suggested guidelines for intraocular lens implant surgery." Archives of Ophthalmology 1977, 94, 214-216.
Jaffe, N.S. "The way things were and are: changing indications for intraocular lens implantation." Ophthalmology, 1983, 90(4), 338-350.
Jaffe, N.S. "The current status of intraocular lenses." Geriatric Ophthalmology, 1985, 37-46.
McDonnell, P.J., Green, W.R. "Pathology of intraocular lens in 33 eyes examined postmortem." Ophthalmology, 1983, 90(4), 398-402.
Hilbig, Harold. "The origin and objectives of intraocular lenticular implants." American Academy of Ophthalmology an Otolaryngology. Transactions, 1976, 8, 65-66.
Symposium: Intraocular Lenses.
Choyce, D.P. "The Lancaster Lens." Medical Lens Manual. Santa Maria, CA: Shepard Inc., 1982.
Lentes da câmara anterior
Boerner, C.F., Thrasher, Jr., B.H. "Complications from Anterior Chamber Lenses: Report of Cases." Archives of Ophthalmology, 93, 1-4, January 1975.
Choyce, D.P. "The Elliot Facts and Figures on Anterior Chamber Lens Implants." Read Before Royal Soc. of Medicine in Biotoc/May 13, 1976.
Duffin, R.M., Olson R.J. "Vaulting Characteristics of Flexible Loop Anterior Chamber Intraocular Lenses." Archives of Ophthalmology, 98, 1429-33 September 1980.
Hagan, 3rd, J.C. "A Comparative Study of the 9/12 and Other Anterior Chamber Intraocular Lenses." Journal of the American Intraocular Implant Society, 10, 3, 324-8, Summer 1984.
Kraff, M.C., Sanders, D.R., Lieberman, H.L. "300 Primary Anterior Chamber Lens Implantations" Gynecologic Findings and Gynecologic Microscopy." Journal of the American Intraocular Implant Society, 5, 207-D, July 1979.
Sakz, J.I., Jones, C.L. "234 Anterior Chamber Implants. Visual Results, Complications and Gonioscopy." Transactions of the American Intraocular Implant Society, 10, 3, 324-8, Summer 1984.
Shammas, H.K., Milikie, C.F. "Primary vs. Secondary Insertion of Anterior Chamber Lenses." Journal of the American Intraocular Implant Society, 5, 2, 141-2, April 1979.
Tennant, J.L. "Results of Primary and Secondary Implants Using Choyce Mark VIII Lenses." Ophthalmic Surgery, Vol. 8, No. 3, 54-56, June 1977.
Glaucoma pós-cirúrgico
Binkhorst, R.D. Intraocular Lens Power Calculation Manual. New York: Richard D. Binkhorst, 1979.
Donzis, P.B., et al. "An intraocular lens formula for short, normal and long eyes." CLAO Journal, 1985, 11(2), 96-98.
Gills, J.P. "Minimizing postoperative refractive errors." Contact Lens, 1980, 6(1), 56-59.
Hoffer, K.J. "Improving the predictability of intraocular lens power calculations." Arch. Ophthalmology, 1984, 91(1), 52-55.
Holladay, J.T., et al. "Improving the predictability of intraocular lens power calculations." Arch. Ophthalmology, 1986, 104, 539-541.
Jiang, Y., et al. "Analysis of intraocular lens power calculation." American Intraocular Implant Society Journal, 1985, 11, 268-271.
Retzlaff, J. "A new intraocular lens calculation formula." American Intraocular Implant Society Journal, 1985, 11, 153-158.
Sanders, D.R., Kraff, M.C. "Improvement of intraocular lens power using empirical data." American Intraocular Implant Society Journal, 1980, 6(2).

Plexiglas® UF-3 er det registrerat varumärke som tillhör Rohm and Haas Company, Philadelphia, PA.

© 2006 Bausch & Lomb Incorporated Med ensamrätt.

Bausch & Lomb Model 122UV
Intraocular lenses for anterior chamber

PRODUKTINFORMATION
Viktigt: Denna produkt får endast säljas av eller på rekommendation av en läkare enligt amerikanska lag.

PRODUKTBESKRIVNING
Bausch & Lomb Incorporated's Modell 122UV-serie intraokulära linser för den främre kammaren tillverkad av Bausch & Lomb Incorporated består av optiska implantat som ersätter den naturliga ögonlinsen som avlägsnats som del av en kirurgisk ingrepp. Linserna tillverkas av Plexiglas® UF-3, ett polymetylmetakrylat (PMMA) som förstärkts med ett UV-absorberande pigment. Data som specifikt avser varje modell finns att tillgå på begäran. Alla övriga uppgifter i denna bilaga gäller alla modeller i Bausch & Lomb Incorporated's Modell 122UV-serie av intraokulära linser för den främre kammaren. Linsens styrka är lättvattenlösning. Linsen har en rätlinjedesign om 1,4 mm, en specifik vikt på 1,19 och en transmission av synligt ljus på 91,0% eller mer. Vågbredden för skärningspunkten på 10 % transmission för UV-ljus är 370 nm för en linsi med +4,0 dioptrier och 388 nm för en linsi med +34,0 dioptrier.

Bausch & Lomb Incorporated Model 512UV eller L1122UV intraokulaar linse for fremme kammer er lille og gjennomsnitlig og innholder en bikonveks optisk linse som skal implanteres i den fremre kammer efter intra- eller ekstracapsulær kataraktekstraktion.

Bausch & Lomb Incorporated's intraocular lens for the anterior chamber is available in the following dioptre powers (in situ): –4,5 to +45,0 dioptre in 1,0 dioptre steps.

Bausch & Lomb Incorporated intraocular lenses are sterile. Den indre pakkningen er sterilisert efter pakking, og skal bare åpnes under sterile forhold.

MEKANISKE EGENSKAPER

MODELLNUMMER	512UV	121UV
Total linsediameter	12,5 mm	13,75 mm
KOMPRESJONSDATA		
Den kraft som kreves for komprimere en linsediameter 0,5 mm mindre enn den opprinnelige diameter etter at den er komprimert ved oppbevaring i 24 timer ved 37° C i deionisert vann.	0,172 g.	0,198 g.
Den kraft som kreves for å komprimere linsediameteren i det omfang som maksimalt forventes ved klinisk bruk.	0,199 g ved 12,00 mm	0,201 g ved 13,75 mm
Den kraft som kreves for å komprimere linsediameteren i det omfang som maksimalt forventes ved klinisk bruk.	0,199 g ved 12,00 mm	0,201 g ved 13,75 mm
Den kraft som kreves for å komprimere linsediameteren i det omfang som maksimalt forventes ved klinisk bruk.	0,199 g ved 12,00 mm	0,201 g ved 13,75 mm

BILDOGRAFI
Generell
Apple, D.J., et al. "Evolution of intraocular lenses." Ophthalmology, 1985, 1-23
Boettner, E.A. and Wolter, J.R. "Transmission of the ocular media." Invest. Ophthal., 1962, 1: 776-783-curve #2 of Figure 5.
Holladay, J.T., et al. "The ideal intraocular lens." CLAO Journal, 1983, 9(1), 15-19.
Jaffe, N.S. "Suggested guidelines for intraocular lens implant surgery." Archives of Ophthalmology 1977, 94, 214-216.
Jaffe, N.S. "The way things were and are: changing indications for intraocular lens implantation." Ophthalmology, 1983, 90(4), 338-350.
Jaffe, N.S. "The current status of intraocular lenses." Geriatric Ophthalmology, 1985, 37-46.
McDonnell, P.J., Green, W.R. "Pathology of intraocular lens in 33 eyes examined postmortem." Ophthalmology, 1983, 90(4), 398-402.
Hilbig, Harold. "The origin and objectives of intraocular lenticular implants." American Academy of Ophthalmology an Otolaryngology. Transactions, 1976, 8, 65-66.
Symposium: Intraocular Lenses.
Choyce, D.P. "The Lancaster Lens." Medical Lens Manual. Santa Maria, CA: Shepard Inc., 1982.
Lentes da câmara anterior
Boerner, C.F., Thrasher, Jr., B.H. "Complications from Anterior Chamber Lenses: Report of Cases." Archives of Ophthalmology, 93, 1-4, January 1975.
Choyce, D.P. "The Elliot Facts and Figures on Anterior Chamber Lens Implants." Read Before Royal Soc. of Medicine in Biotoc/May 13, 1976.
Duffin, R.M., Olson R.J. "Vaulting Characteristics of Flexible Loop Anterior Chamber Intraocular Lenses." Archives of Ophthalmology, 98, 1429-33 September 1980.
Hagan, 3rd, J.C. "A Comparative Study of the 9/12 and Other Anterior Chamber Intraocular Lenses." Journal of the American Intraocular Implant Society, 10, 3, 324-8, Summer 1984.
Kraff, M.C., Sanders, D.R., Lieberman, H.L. "300 Primary Anterior Chamber Lens Implantations" Gynecologic Findings and Gynecologic Microscopy." Journal of the American Intraocular Implant Society, 5, 207-D, July 1979.
Sakz, J.I., Jones, C.L. "234 Anterior Chamber Implants. Visual Results, Complications and Gonioscopy." Transactions of the American Intraocular Implant Society, 10, 3, 324-8, Summer 1984.
Shammas, H.K., Milikie, C.F. "Primary vs. Secondary Insertion of Anterior Chamber Lenses." Journal of the American Intraocular Implant Society, 5, 2, 141-2, April 1979.
Tennant, J.L. "Results of Primary and Secondary Implants Using Choyce Mark VIII Lenses." Ophthalmic Surgery, Vol. 8, No. 3, 54-56, June 1977.
Glaucoma pós-cirúrgico
Binkhorst, R.D. Intraocular Lens Power Calculation Manual. New York: Richard D. Binkhorst, 1979.
Donzis, P.B., et al. "An intraocular lens formula for short, normal and long eyes." CLAO Journal, 1985, 11(2), 96-98.
Gills, J.P. "Minimizing postoperative refractive errors." Contact Lens, 1980, 6(1), 56-59.
Hoffer, K.J. "Improving the predictability of intraocular lens power calculations." Arch. Ophthalmology, 1984, 91(1), 52-55.
Holladay, J.T., et al. "Improving the predictability of intraocular lens power calculations." Arch. Ophthalmology, 1986, 104, 539-541.
Jiang, Y., et al. "Analysis of intraocular lens power calculation." American Intraocular Implant Society Journal, 1985, 11, 268-271.
Retzlaff, J. "A new intraocular lens calculation formula." American Intraocular Implant Society Journal, 1985, 11, 153-158.
Sanders, D.R., Kraff, M.C. "Improvement of intraocular lens power using empirical data." American Intraocular Implant Society Journal, 1980, 6(2).

Plexiglas® UF-3 er det registrerede varemærke som tilhører Rohm and Haas Company, Philadelphia, PA.

© 2006 Bausch & Lomb Incorporated Ret forbehold.

Bausch & Lomb Model 122UV
Intraocular lenses for anterior chamber

PRODUKTINFORMATION
Vaarsoq! Taamaattorlu iittuvallimik makuusen tikitt talietta saa myydä vain lääkäri tai lääkärin määräyksestä.

LIITTEEN MUODOSTAMA
Bausch & Lomb Incorporated-valmistamat Bausch & Lomb Incorporated Model 122UV-sarjan intraokulaarisen linsseistä koostuvat ihmisen luonnollisen silmänsisäisen linsseistä poistettuja sairauksia varten. Linsseistä on valmistettu Plexiglas® UF-3, polymetyylimetakrylaatti (PMMA) sun forsteds med ultraviolettabsorberende pigment. Data som specifikt avser varje modell finns att tillgå på begäran. Alla andra uppgifter i denna bilaga gäller alla modeller i Bausch & Lomb Incorporated's Modell 122UV-serie av intraokulära linser för den främre kammaren. Linsens styrka är lättvattenlösning. Linsen har en rätlinjedesign om 1,4 mm, en specifik vikt på 1,19 och en transmission av synligt ljus på 91,0% eller mer. Vågbredden för skärningspunkten på 10 % transmission för UV-ljus är 370 nm för en linsi med +4,0 dioptrier och 388 nm för en linsi med +34,0 dioptrier.

Bausch & Lomb Incorporated Model 512UV eller L1122UV intraokulaar linse for den fremre kammer er lille og gjennomsnitlig og indeholder en bikonveks optisk linse som skal implanteres i den fremre kammer efter intra- eller ekstracapsulær kataraktekstraktion.

Bausch