註 (1)報核仿單標籤以粘貼全型實物為原則。
(2)仿單標籤等實物過大或印於玻璃金屬容器等不便於粘貼時附送現品並將照相影本代替粘貼報核。

"視導" 人工水晶體眼球
"Storz" Intraocular Lense

衛署醫器輸字第 009172 號

設計說明：
"Storz" 眼科公司生產之人工水晶體可預防紫外線，其功能爲取代人體失效之水晶體，幫助無晶體病人恢復視覺，人工水晶體適用於六十歲以上白內障摘除水晶體之病人。後房人工水晶體適用於施行囊外水晶體摘除術。前房人工水晶體適用於施行囊內水晶體摘除術或是二次囊外水晶體摘除術。材質爲 polymethylmethacrylate (PMMA)，添加抗紫外線成份，成爲防紫外線產品。度數範圍自＋4.0 至＋34.0 每 0.5 度爲度數間隔。

不適應性：
病患有下列症狀或狀況者應避免施行人工水晶體植入手術以免造成病情惡化或影響治療效果：先天性雙眼白內障患者；前房或後房因不知病因發炎之病人；病人前房距離過短，如慢性閉角性青光眼；病人植入人工水晶體後，會妨礙後房病變之觀察診斷及治療；手術摘除晶體時有併發症產生者，如大量出血，虹膜受損，無法完全清除前房之玻璃體，後房眼壓過高無法控制，玻璃體大量流失或前房出血；僅有一眼有恢復知覺的可能；無法用醫療法控制之青光眼；角膜內皮失養症；糖尿病造成之視網膜增生病變。

警告：
任何外科手術皆有其危險性，白內障摘除或人工水晶體之植入均可能發生併發症，如晶體移位、無色素沉澱、角膜內膜細胞受損、眼內壓過高、感染、視網膜剝離、玻璃體發炎、囊性斑浮腫、角膜浮腫、瞳孔覆膜、前房塌陷、虹膜脫出、前房積腫及繼發性青光眼。

人工水晶體之植入爲非常狀態下的眼睛，其安全性無法確知。(如慢性藥物縮瞳、青光眼、弱視、糖尿病造成的視網膜病變，曾經角膜移植，曾發生視網膜剝離或虹膜炎等)；有上述症狀之病人在植入人工水晶體前應先考慮以其他方式矯正。前房人工水晶體植入可能造成以下反應：前房積膿、急性角膜代償失調、晶體移位、接觸角膜導致晶體移除、感染導致晶體移除、晶體替換、瞳孔阻斷導致玻璃體吸出及瞳孔阻斷導致虹膜切除。

植入晶體的病人其效果尚未確認前應需長期術後追蹤。

在老化斑點及視網膜退化之病人眼中植入人工水晶體，可能無法產生預期效果。
有青光眼或角膜疾患之病人植入後，曾偶發繼發性青光眼，需在術後長期注意眼壓的變化。

病人在晶體切除中，曾有後囊破裂台斯梅氏膜剝離前房出血虹膜受損玻璃體膨出或流出等情況發生，術後需密切追蹤。

後房水晶體不適於植入前房，有安全的顧慮。

應避免瞳孔的二次虹膜切開。

防止紫外線的晶體無法減少視網膜移位的發生率。

少數晶體偏心，發生小或狹窄視力，使病人在這種光線下產生閃爍或其他視覺障礙，醫師在植入前，需事先考量。

警告：
1. 不可重覆消毒使用。
2. 不要直接儲存在日光照射或超過 40°C。
3. 不要用非等張平衡鹽類的溶液清洗。
4. 植入人工水晶體需具備純熟的手術技術。

5. 不可使用已破損或開啓無菌包裝的人工水晶體。
6. 手術前醫師需告知病人手術所可能引起的相關併發症。

如何使用：

本產品爲無菌乾燥包裝，內部無菌包裝應在無菌下開封。

使用方法：

- 打開外包裝，在無菌區小心取出晶體。
- 注意因爲晶體和包裝的材質爲塑膠晶體在打開後會與外包裝產生靜電故需小心檢視避免附著。
- 晶體應使用光學鑷取出，不應使用可鎖鉗子或持線器。
- 不要用非等張平衡鹽類的溶液清洗及浸泡。
- 晶體應小心夾取避免外界物質或顆粒附著。
- 本產品請勿彎曲，或扭轉以避免折斷。
- 植入前應檢視晶體的型式，能源及光學表面。

型號種類： 102. 10. 29

型號	晶面設計	晶體大小	長度	支腳角度	支腳設計	A常數	紫外線	特性
68-UV	雙凹	6.0mm	13.75mm	5.9°	C型	118.0 4.96mm	可吸收 紫外線	廣泛度數
127-UV	雙凹	7.0mm	13.75mm	10°	C型	118.5 5.26mm	可吸收 紫外線	多方位彈性
95-UV	雙凹	7.0mm	13.75mm	10°	C型	118.0 4.96mm	可吸收 紫外線	多方位彈性
P010-UV	雙凹	6.5mm	13.75mm	10°	C型	118.0 4.96mm	可吸收 紫外線	多方位彈性
P359-UV	雙凹	5.5mm	12.25mm	2.4°	C型	118.0 4.96mm	可吸收 紫外線	多方位彈性
P329-UV	雙凹	5.0×6.0	12.0mm	7.6°	C型	118.4 5.2mm	可吸收 紫外線	多方位彈性
P366-UV	雙凹	6.5mm	13.4mm 12.0mm	6.6°	C型	118.5 5.26mm	可吸收 紫外線	多方位彈性
S122UV	雙凹	6.0mm	12.50mm	4.4°	S型	115.8 3.68mm	可吸收 紫外線	四定位固定
BV359	雙凹	5.5mm	12.25mm	2.4°	C型	118.0 4.96mm	可吸收 紫外線	藍色支腳
BVR150S	雙凹	5.0mm	12.25mm	2.8°	C型	118.1 5.02mm	可吸收 紫外線	多方位彈性 藍色支腳
BVR155S	雙凹	5.5mm	12.25mm	3.1°	C型	118.1 5.02mm	可吸收 紫外線	多方位彈性 藍色支腳
BVR160M	雙凹	6.0mm	12.75mm	3°	C型	118.1 5.02mm	可吸收 紫外線	多方位彈性 藍色支腳
BVR165L	雙凹	6.5mm	13.25mm	3°	C型	118.1 5.02mm	可吸收 紫外線	多方位彈性 藍色支腳
EZE-50	雙凹	6.0mm	12.75mm	2.9°	C型	118.1 5.02mm	可吸收 紫外線	多方位彈性 雙階梯支腳
EZE-55	雙凹	5.5mm	12.75mm	3°	C型	118.1 5.02mm	可吸收 紫外線	多方位彈性 雙階梯支腳
EZE-65	雙凹	6.5mm	13.25mm	3°	C型	118.1 5.02mm	可吸收 紫外線	多方位彈性 雙階梯支腳
P484-UV	雙凹	6.5mm	13.00mm	10°	C型	117.9 4.91mm	可吸收 紫外線	多方位彈性
P517-UV	雙凹	6.5mm	13.25mm	3°	C型	118.0 4.96mm	可吸收 紫外線	多方位彈性 廣泛度數
P574-UV	雙凹	6.0mm	13.25mm	3°	C型	118.1 5.02mm	可吸收 紫外線	多方位彈性 廣泛度數

註銷規格 註銷規格 註銷規格 註銷規格

102. 10. 29

製造廠名稱 ： **STORZ OPHTHALMICS. INC.**
21 Park Place Boulevard North,
Clearwater, FL 34619
U.S.A.

藥商名稱 ： **實敦企業股份有限公司**
藥商地址 ： **台北市建國北路一段 96 號 13 樓**
電　　話 ： **(02) 2500-2598**

衛 02011

仿單標籤粘

產品名稱	"視導"人工水晶体眼内請廠
衛生署給證號碼	衛署醫器輸 字第

88. 8. 11

Storz Oph

STORZ UV-ABSORBING POSTERIOR AND ANTERIOR CHAMBER INTRAOCULAR LENSES

PRODUCT IDENTITY AND INDICATIONS

Storz ultraviolet absorbing posterior and anterior chamber intraocular lenses manufactured by Storz Ophthalmics Inc., are optical implants for the replacement of the human crystalline lens. Storz intraocular lenses are indicated for primary implantation for the visual correction of aphakia in patients 60 years of age or older where a cataractous lens has been removed. Posterior chamber lenses are indicated after cataract removal by extracapsular extraction methods. Anterior chamber lenses are indicated subsequent to either a primary intra- or extracapsular cataract extraction or after prior surgery such that a secondary implant procedure is required. Storz intraocular lenses are made from polymethylmethacrylate (PMMA) with a UV absorbing compound added. Lenses are available in powers (in situ) from +4.0 to +34.0 diopters in 0.5 diopter increments.

CONTRAINDICATIONS

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; patients with 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; for anterior chamber implantation, previous history of, or 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 clean the anterior chamber of vitreous, uncontrollable positive pressure, significant vitreous loss, or significant anterior chamber bleeding; only one eye with potentially good vision; medically uncontrollable glaucoma; corneal endothelial dystrophy; proliferative diabetic retinopathy.

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, nonpigment precipitates, corneal endothelial damage, high intraocular pressure, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary membranes, flat anterior chamber, iris prolapse, hypopyon, and secondary glaucoma.

The safety of intraocular lens implantation has not been substantiated in patients with pre-existing ocular conditions (chronic drug miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, history of retinal detachment or iritis, etc.). Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory to meet the needs of the patient. Some adverse reactions which have been associated with the implantation of anterior chamber 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, iridectomy for pupillary block.

The long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor implant patients post-operatively on a regular basis.

Principal Investigator

Last

Lens Model #

Lens Control #

"視導" 人工

衛署醫器輸

藥商: 寶敦企業股份有限公司

地址: 台北市建國北路 1 段 96

有效日期及製造批號請見外盒

※外文仿單應檢附中文譯本

衛 02011

仿單標籤粘貼表

產品名稱	"視導"人工水晶体眼	申請廠商	博士
衛生署給證號碼	衛署醫器輸	字第	009

88. 8. 11

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 posterior chamber lens implants. The intraocular pressure of implant patients with ocular pathology should be carefully monitored postoperatively.

Hyphema, macular edema and vitritis have been reported in patients who experience surgical complications associated with the cataract extraction procedure (posterior capsule rupture, detached Descemet's membrane, anterior chamber bleeding, iris damage, and vitreous bulge or loss). Patients who experience operative complications should be carefully monitored postoperatively for the occurrence of these complications.

The safety and effectiveness of a posterior chamber lens, if placed in the anterior chamber, have not been established. Implantation of posterior chamber lenses in the anterior chamber has been shown in some cases to be unsafe.

The need for a secondary iridectomy for pupillary block may be prevented by one or more iridectomies at the time of intraocular lens implantation.

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

Some Storz intraocular lenses are manufactured with optics that are 5.00mm. Small amounts of lens decentration occurring with an intraocular lens having a narrow or small optic may result in the patient experiencing glare or other visual disturbances under certain lighting conditions. Surgeons should consider this potential before implanting an intraocular lens with a small or narrow optic.

PRECAUTIONS

1. Do not attempt to resterilize this lens.
2. Do not store the lens in direct sunlight or at temperatures greater than 40°C. Keep from freezing.
3. Do not soak or rinse lens in solutions other than balanced salt solution or equivalent.
4. A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and/or assisted in numerous surgical implantations and should have completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
5. Do not use if sterile pouch is opened or damaged.
6. The patient must be advised that the doctor or the medical center should be informed of any side effects not referred to in the information the patient received prior to surgery.

HOW SUPPLIED

Storz intraocular lenses are supplied STERILE in a dry, heat-sealed package. The inner package is terminally sterilized and should be opened only under sterile conditions.

DIRECTIONS FOR USE

To remove the lens, peel open the outer pouch 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 optic, using smooth-edged forceps, and lifting. Locking forceps or needle holders should never be used.

Do not soak or rinse the lens in solutions other than balanced salt solutions or their equivalent.

The lens should be carefully examined to insure that particles have not adhered to it.

Storz one-piece PMMA lenses are designed to compress in the plane of the lens only. To avoid breakage, do not attempt to expand the haptics, flex the haptics out of the plane of the lens or twist or torque the lens.

Prior to implantation, examine the lens for type, power, proper configuration and optical surfaces.

Storz Ophthalmics' si... to yo... for in...

LVD. ... 33759

STO

...l (USA ...rned to ...st, or d...

Yea...

OS

Principal Investigator

Last

Lens Model #

Lens Control #

ATTACH ST...

"視導" 人工...

衛署醫器輸...

藥商: 寶敦企業股份有限公司

地址: 台北市建國北路 1 段 96 ... 13 樓

有效日期及製造批號請見外盒

※外文仿單應檢附中文譯本

衛 02011

仿單標籤粘貼

產品名稱	"視導"人工水晶体眼睛	請廠商	博士
衛生署給證號碼	衛署醫器輸	字第	009

88. 8. 11

88. 8. 11

Storz Ophthalmics'

for

STORZ UV-ABSORBIERENDE HINTER- UND VORDERKAMMER INTRAOKULARLINSEN

PRODUKTBESCHREIBUNG

Storz UV-absorbierende Hinter- und Vorderkammerlinsen sind optische Implantate für den Ersatz der natürlichen kristallinen Linse. Storz Intraokularlinsen sind zur Primärimplantation als Korrektur von Aphakie bei Patienten im Alter von mindestens 60 Jahren indiziert, deren getrübte natürliche Linse entfernt wurde.

Hinterkammerlinsen sind indiziert nach Entfernug der getrübten Linse durch extrakapsuläre Extraktion. Vorderkammerlinsen sind indiziert nach Entfernung der getrübten Linse durch intra- oder extrakapsuläre Extraktion oder in Fällen einer sekundären Implantation.

Storz Intraokularlinsen werden aus Polymethylmethacrylat (PMMA) hergestellt unter Zusatz einer UV-absorbierenden Komponente.

Storz Intraokularlinsen sind standardmäßig in Stärken von +4,0 bis +34,0 Dioptrien mit Abstufungen von 0,5 Dioptrien erhältlich.

GEGENANZEIGEN

Patienten, für die eine oder mehrere der nachfolgend aufgeführten Gegenanzeigen zutrifft, könnten für die Implantation einer Intraokularlinse ungeeignet sein, da ein bereits bestehender Zustand verschlimmert oder die Behandlung eines Zustandes beeinträchtigt werden könnte oder die Implantation ein unangemessenes Risiko für das Augenlicht des Patienten bedeuten würde.

- beidseitige kongenitale Katarakte;
- wiederholte Entzündungen des vorderen oder hinteren Segmentes unbekannter Ursache in der Vorgeschichte;
- verkürztes Vordersegment, wie z.B. Mikrophthalmus oder bestimmte Formen des Winkelblockglaukoms;
- bei Implantation von Vorderkammerlinsen: vorangegangene Netzhautablösung oder Prädisposition dafür.
- Patienten, bei denen die Intraokularlinse die Möglichkeit der Beobachtung, Diagnostizierung oder Behandlung von Hintersegmentkrankheiten beeinträchtigen könnte;
- Probleme während der Kataraktextraktion, die das Risiko möglicher Komplikationen erhöhen könnten, wie z.B. andauernde Blutung, erhebliche Verletzung der Iris, nicht entfernbare Glaskörperflüssigkeit in der Vorderkammer, nicht kontrollierbarer überhöhter Augeninnendruck, erheblicher Glaskörperverlust oder Vorderkammerblutung;
- Patienten mit nur einem voll funktionsfähigen Auge;
- medikamentös unkontrollierbares Glaukom;
- endotheliale Hornhautdystrophie;
- proliferative diabetische Retinopathie;

WARNHINWEISE

Wie bei jedem chirurgischen Eingriff besteht auch hier ein Risiko. Zu den potentiellen Komplikationen der Kataraktoder Implantationschirurgie zählen u.a.:

Dislokation der Linse, nicht-pigmentöse Ablagerungen, Schäden des Hornhautendotheis, erhöhter Augeninnendruck, Infektionen (Endophthalmitis), Netzhautablösung, Vitritis, zystoides Makulaödem, Hornhautödem, Pupillenmembran, flache Vorderkammer, Irisprolaps, Hypopyon und Sekundärglaukom.

Die Sicherheit der Intraokularlinsenimplantation wurde bei Patienten mit bestehenden Augenleiden nicht belegt (chronische medikamentöse Miosis, Glaukom, Amblyopie, diabetische Retinopathie, vorangegangene Hornhauttransplantation, Netzhautablösung oder Iritis in der Vorgeschichte, etc.). Erwägt ein Arzt eine Linsenimplantation bei solchen Patienten, so sollte er alternative Methoden der Aphakiekorrektur in Betracht ziehen und eine Linsenimplantation nur dann ins Auge fassen, wenn andere Alternativen den Anforderungen des Patienten nicht genügen.

Folgende Gegenreaktionen und Konsequenzen wurden in Zusammenhang gebracht mit der Implantation von Vorderkammerlinsen: Hypopyon, akute Hornhautdekompensation, Repositionierung der Linse, Entfernung der Linse aufgrund von Hornhautpalpation, entzündungsbedingte Entfernung der Linse, Hornhauttransplantation, Intraokulare Infektion, Austausch der implantierten Linse, Glaskörperextraktion und Iridektomie aufgrund eines Pupillarblocks.

Langzeiterfahrungen zur Linsenimplantation liegen noch nicht vor, daher sollten Patienten mit Intraokularlinsen postoperativ in regelmäßigen Abständen beobachtet werden.

Bei Patienten mit altersbedingter Makula- oder Retinadegeneration sollte in Erwägung gezogen werden, daß möglicherweise keine Verbesserung der zentralen Sehschärfe zu erwarten ist.

Patienten mit augenpathologischem Befund, wie z.B. Glaukom oder Hornhauterkrankungen erreichen ggf. nicht die gleiche Sehschärfe wie Patienten ohne Befund. Gelegentlich wurde über das Auftreten von Sekundärglaukom bei Patienten mit kontrolliertem Glaukom nach der Implantation von Hinterkammerlinsen berichtet. Der Augeninnendruck von Implantationspatienten mit augenpathologischem Befund sollte postoperativ sorgfältig beobachtet werden.

Gelegentlich traten als Folge intraoperativer Komplikationen bei der Kataraktextraktion (wie z.B. Kapselriß, Ablösung der Descemet-Membran, Vorderkammerblutung, Beschädigung der Iris, Glaskörperschwellung oder -verlust) postoperative Probleme wie Makulaödem, Hyphaema oder auch Vitritis auf, daher sollten solche Patienten postoperativ sorgfältig überwacht werden.

Bei Implantation einer Hinterkammerlinse in die Vorderkammer kann die Sicherheit und Wirksamkeit nicht gewährleistet werden, da sich die Implantation von Hinterkammerlinsen in die Vorderkammer in einigen Fällen als unsicher erwiesen hat.

Die Notwendigkeit einer sekundären Iridektomie kann durch eine oder mehrere Iridektomien während der IOL-Implantation umgangen werden.

Die Wirksamkeit von UV-hemmenden Intraokularlinsen im Zusammenhang mit Problemen der Retina ist nicht erwiesen.

Einige Storz Intraokularlinsen-Modelle haben eine Optik von 5,0 mm. Bei Intraokularlinsen mit einer kleinen Optik kann schon eine leichte Dezentrierung der Linse unter bestimmten Lichteinflüssen zu Beeinträchtigungen des Sehvermögens oder Blendungserscheinungen führen. Dies sollte vor Implantation einer Intraokularlinse mit kleiner Optik in Erwägung gezogen werden.

Principal Investigator
Last

Lens Model #

Lens Control #

ATTAC

"視導" 人工

衛署醫器輸

藥商: 寶敦企業股份有限公司

地址: 台北市建國北路 1 段 96

有效日期及製造批號請見外盒

※外文仿單應檢附中文譯本

Storz Ophthalm

VORSICHTSMASSNAHMEN

1. Nicht resterilisieren.
2. Linsen weder direkter Sonneneinstrahlung noch Temperaturen über 40°C oder aber unter dem Gefrierpun aussetzen.
3. Die Linse nur mit gepufferter Kochsalzlösung (BSS) oder einer gleichwertigen Lösung spülen.
4. Die Implantation von Intraokularlinsen erfordert großes chirurgisches Geschick, daher sollte der implantierend Chirurg möglichst viel Erfahrung durch Beobachtung und/oder Assistieren bei Implantationen gesamm und mindestens einen entsprechenden Kurs erfolgreich absolviert haben.
5. Intraokularlinsen nicht benutzen, wenn Sterilbeutel geöffnet oder beschädigt ist.
6. Der Patient muß angewiesen werden, den betreuenden Arzt über alle Nebenerscheinungen zu informiere insbesondere solche, auf die nicht bereits im Vorgespräch hingewiesen wurde.

LIEFERFORM

Storz Intraokularlinsen werden steril in einer verschweißten Packung geliefert. Die innere Verpackung wird b Abschluß des Herstellungsprozesses mit sterilisiert und sollte nur unter sterilen Bedingungen geöffnet werde

ANWENDUNGSHINWEISE

- Zur Entnahme der Linse, öffnen Sie den äußeren Beutel und entnehmen den Linsenträger in steriler Umgebun
- Bei transparentem Linsenträger heben Sie den Deckel vorsichtig an, um die Linse freizulegen. Bei graue Linsenträger schieben Sie den transparenten Deckel vorsichtig nach hinten, um die Linse freizulegen.
- Entnehmen Sie die Linse indem Sie die Optik mit einer Implantationspinzette fassen und anheben. Pinzett mit Verschluß oder Nadelhalter sollten in keinem Fall verwendet werden.
- Die Linse nur mit steriler gepufferter Kochsalzlösung (BSS) oder einer gleichwertigen Lösung spülen.
- Die Linse sollte auf etwaige Ablagerungen sorgfältig geprüft werden.
- Die Einstück-PMMA-Linsen von Storz sind so gestaltet, daß sich die Haptiken nur in der Linsenebe zusammendrücken lassen. Um einen Bruch zu vermeiden, versuchen Sie niemals, die Haptiken zu dehn oder sie aus der Linsenebene heraus zu biegen oder die Linse zu verdrehen.
- Überprüfen Sie die Linse vor der Implantation auf Typ, Brechkraft, ordnungsgemäße Konfiguration u einwandfreie optische Oberflächen.

LENTILLES INTRA-OCULAIRES STORZ DE CHAMBRE ANTERIEURE ET POSTERIEURE AVEC FILTRE UV

IDENTIFICATION DU PRODUIT ET INDICATIONS

Les lentilles intra-oculaires STORZ de chambre antérieure et postérieure avec filtre UV sont des implants optiques pour le remplacement du cristallin, et sont fabriquées par Storz Ophtalmics, Inc. Les lentilles intra-oculaires STORZ sont indiquées en implantation primaire pour la correction de l'aphakie chez les patients âgés de plus de 60 ans lorsque le cristallin cataracté a été enlevé.

Les lentilles de chambre postérieure sont indiquées après l'ablation du cristallin par des méthodes d'extraction extracapsulaire. Les lentilles de chambre antérieure sont indiquées à la suite, soit d'une première extraction du cristallin intra ou extracapsulaire, soit d'une première intervention lorsqu'une seconde procédure d'implantation est nécessaire. Les lentilles STORZ sont en polyméthylméthacrylate (PMMA) contenant un filtre UV. Les lentilles sont disponibles en vergences allant de +4 à +34,0 dioptries, de 0,5 en 0,5 dioptrie.

CONTRE-INDICATIONS

L'implantation d'une lentille intra-oculaire est contre-indiquée lorsque la lentille peut accentuer l'état existant, peut interférer avec un traitement concomitant, ou peut provoquer un risque pour la vue du patient :

- cataracte bilatérale congénitale,
- inflammation périodique du segment antérieur ou postérieur d'étiologie inconnue,
- chambre antérieure de faible profondeur (ex. microphtalmie ou certaines formes de glaucome chronique à angle fermé),
- antécédents ou prédispositions au décollement de rétine, pour l'implantation en chambre antérieure,
- patients chez qui la lentille intra-oculaire peut interférer avec la possibilité de diagnostiquer, de prévenir ou de traiter les maladies du segment postérieur,
- difficultés chirurgicales au moment de l'extraction du cristallin qui pourraient augmenter le risque de complications (ex. saignement persistant, dommage significatif sur l'iris, impossibilité de nettoyer le vitré dans la chambre antérieure, pression intra-oculaire positive incontrôlable, fuite vitréenne significative, ou saignement important de la chambre antérieure),
- patients monophtalmes,
- glaucome médicalement incontrôlable,
- dystrophie endothéliale cornéenne
- rétinopathie diabétique prolifératives.

MISES EN GARDE

Il existe un risque lié à toute intervention chirurgicale.

La liste, non exhaustive, des complications potentielles liées à la chirurgie de la cataracte ou à la technique d'implantation est la suivante : décentrement de la lentille, précipités non pigmentés, lésions cornéennes endothéliales, élévation de la pression intra-oculaire, infection (endophtalmie), décollement de la rétine, inflammation du corps vitré, oedème maculaire cystoïde, oedème cornéen, membranes pupillaires, chambre antérieure peu profonde, prolapsus de l'iris, hypopyon et glaucome secondaire.

Principal Investigator
Last

Lens Model #

Lens Control #

※外文仿單應檢附中文譯本

88. 8. 11

產品名稱	視導"人工水晶体眼睛 請廠商
衛生署給證號碼	衛署醫器輸 字第

88. 8. 11

Storz Ophthali

La sécurité de l'implantation d'une lentille intra-oculaire n'est pas établie chez les patients qui présentent des antécédents visuels (myosis chronique médicamenteux, glaucome, amblyopie, rétinopathie diabétique, greffe cornéenne antérieure, antécédent d'un décollement de rétine ou d'iritis, etc,...). Les chirurgiens qui envisagen l'implantation d'une lentille chez de tels patients, doivent évaluer les méthodes alternatives pour la correction de l'aphakie et ne considérer l'implantation d'une lentille que si ces alternatives sont jugées insatisfaisantes pou répondre aux besoins des patients.

Quelques effets indésirables sont liés à l'implantation d'une lentille intra-oculaire de chambre antérieure : hypopyon décompensation cornéenne aigüe, repositionnement de la lentille, retrait de la lentille dû à un contact cornéen retrait de la lentille dû à une inflammation, greffe cornéenne, infection intra-oculaire, replacement de la lentille aspiration du vitré pour blocage pupillaire, iridectomie pour blocage pupillaire.

Les effets à long terme d'une implantation de lentille intra-oculaire n'ont pas été établis. En conséquence, les chirurgiens doivent continuer à suivre les patients après l'intervention de façon régulière.

Chez des patients qui présentent une dégénérescence maculaire ou rétinienne liée à l'âge, il faut noter qu'une amélioration de l'acuité visuelle centrale peut ne pas être observée suite à l'implantation d'une lentille intra oculaire.

Les patients qui ont des pathologies oculaires comme le glaucome, ou des maladies cornéennes, peuvent ne pas récupérer une acuité visuelle identique à celle des autres patients. Il a été rapporté quelques cas de glaucome secondaire chez des patients qui présentaient un glaucome contrôlé et qui ont reçu une lentille intra-oculaire de chambre postérieure.

La pression intra-oculaire chez les patients qui présentent une pathologie oculaire doit être soigneusement suivie après l'implantation.

Des hyphema, des oedèmes maculaires et des inflammations du corps vitré ont été observés chez les patients ayant eu des complications lors d'intervention chirurgicale de la cataracte (rupture de la capsule postérieure détachement de la membrane de Descemet, saignement dans la chambre antérieure, dommage de l'iris, hernie du vitré, ou perte de vitré). Ces patients doivent être suivis soigneusement en post-opératoire.

La sécurité et l'efficacité d'une lentille de chambre postérieure, implantée en chambre antérieure, n'ont pas été évaluées. Des effets indésirables ont été observés dans quelques cas.

La nécessité d'une iridectomie secondaire pour un blocage pupillaire peut être évitée par une ou plusieurs iridectomies au moment de l'implantation de la lentille intra-oculaire.

L'efficacité des lentilles intra-oculaires contenant un filtre UV n'a pas été évaluée dans la diminution de l'incidence des complications rétiniennes.

Quelques modèles de lentilles intra-oculaires STORZ sont fabriqués avec une optique de 5,00 mm. Un décentrement de la lentille est possible avec ces lentilles d'optique étroite ou petite, pouvant être à l'origine d'éblouissement ou de gêne visuelle dans certaines conditions lumineuses. Le chirurgien devra tenir compte de ce phénomène avant d'implanter de telles lentilles.

PRECAUTIONS

1. Ne jamais restériliser la lentille.
2. Ne pas stocker la lentille à la lumière directe du soleil ou à des températures supérieures à 40°C. Ne pas réfrigérer.
3. Tremper ou rincer la lentille uniquement avec des solutions salines ou un équivalent.
4. Un haut niveau de compétence chirurgicale est nécessaire pour implanter des lentilles intra-oculaires. Le chirurgien doit avoir assisté et participé à de nombreuses implantations chirurgicales et doit avoir suivi des cours sur l'implantation des lentilles intra-oculaires avant de pratiquer.
5. Ne pas utiliser si le sachet stérile est ouvert ou endommagé.
6. Le patient doit être averti par son médecin ou son centre médical des effets indésirables potentiels liés à toute intervention.

PRESENTATION

Les lentilles intra-oculaires STORZ sont fournies STERILES dans un emballage sec, scellé à chaud. L'emballage intérieur est stérilisé et ne peut être ouvert qu'en milieu stérile.

INSTRUCTIONS D'UTILISATION

- Pour retirer la lentille, rompre le sachet externe et extraire le support dans des conditions aseptiques.
- Dans le cas d'un support transparent: Soulever doucement le couvercle du support pour retirer la lentille. Dans le cas d'un support gris: Tirer doucement vers l'arrière le couvercle du support.
- Pour extraire la lentille du support, saisir l'optique avec le bout de la pince à implantation; puis soulever la lentille. Des pinces verrouillables ou des porte-aiguilles ne doivent jamais être utilisés.
- Tremper ou rincer la lentille uniquement avec des solutions salines ou un équivalent.
- La lentille doit être soigneusement examinée afin de vérifier l'absence de dépôt de particules.
- Les lentilles monoblocs STORZ en PMMA sont conçues pour subir des compressions uniquement dans le plan de la lentille. Afin d'éviter toute rupture, ne pas essayer de tordre les anses en dehors du plan de la lentille ou de tordre la lentille.
- Avant l'implantation, vérifier la lentille : le modèle, la puissance, la configuration de l'implant et les surfaces optiques.

Principal Investigator
Last

Lens Model #

Lens Control #

"視導" 人工

衛署醫器輸

製商: 寶敦企業股份有限公司

地址: 台北市建國北路 1 段 96 號 13 樓

有效日期及製造批號請見外盒

※外文仿單應檢附中文譯本

衛 02011

仿單標籤粘

88. 8. 11

產品名稱	視導"人工水晶体服	請
衛生署給證號碼	衛署醫器輸	字第

88. 8. 11

Storz O

LENTI INTRAOCULARI DA CAMERA ANTERIORE E POSTERIORE STORZ CON FILTRAGGIO DELLA RADIAZIONE U.V.

IDENTIFICAZIONE DEL PRODOTTO E INDICAZIONI

Le lenti intraoculari da camera anteriore e posteriore Storz con filtraggio della radiazione U.V. prodotte dalla STORZ OPHTHALMICS Inc. sono impianti ottici per la sostituzione del cristallino umano.

Le lenti intraoculari Storz sono indicate come impianto primario per la correzione visiva della afachia in pazienti di 60 anni di età o più anziani nei quali è stato rimosso il cristallino cataratto so.
Le lenti da camera posteriore sono indicate dopo la rimozione della cataratta con i metodi di estrazione extracapsulare.

Le lenti da camera anteriore sono indicate a seguito sia di un impianto primario con estrazione intra- o extra capsulare della cataratta sia dopo una chirurgia che richieda un impianto secondario.
Le lenti intraoculari Storz sono fatte in polimetilmetacrilato (PMMA) con l'aggiunta di un composto chimico in grado di assorbire le radiazioni U.V.

Le lenti sono disponibili nei poteri (in situ) fra +4 e + 30 diottrie con incrementi di 0.5 diottrie.

CONTROINDICAZIONI

Pazienti con alcune delle seguenti condizioni possono non essere considerati candidati idonei per una lente intraoculare in quanto la lente potrebbe esasperare una condizione esistente, interferire con il trattamento di una situazione o porre un irragionevole rischio per la vista del paziente: cataratte bilaterali congenite, pazienti con ricorrente infiammazione del segmento anteriore o posteriore di sconosciuta etiologia, pazienti con segmenti anteriori dell'occhio accorciati (ad es. microftalmo, alcune forme di glaucoma cronico ad angolo chiuso ecc.), per impianto in camera anteriore con precedenti o predisposizioni per distacco di retina, pazienti nei quali la lente intraoculare può interferire con la capacità di osservare, diagnosticare o trattare malattie del segmento posteriore, difficoltà chirurgiche al momento dell'estrazione della cataratta che potrebbero aumentare il potenziale per le complicanze (per es. sanguinamento persistente, significativi danni iridei, incapacità di rimuovere il vitreo dalla camera anteriore, pressione positiva fuori controllo, significative perdite di vitreo o sanguinamenti della camera anteriore), soltanto un occhio con potenziale buona visione, glaucoma farmacologicamente incontrollabile, distrofia dell'endotelio corneale, retinopatia diabetica proliferante.

AVVERTENZE

Come in ogni altra procedura chirurgica ci sono dei rischi coinvolti con essa.

Potenziali complicanze che accompagnano la chirurgia della cataratta e dell'impianto possono includere, ma non sono limitate alle seguenti: dislocazione della lente, precipitati non pigmentati, danni all'endotelio corneale, alta pressione intraoculare, infezioni (endoftalmiti), distacco di retina, vitriti, edema cistoide maculare, edema corneale, membrane pupillari, camera anteriore piatta, prolasso irideo, hypopion e glaucoma secondario.

La sicurezza di un impianto di lente intraoculare non è stata sostanziata in pazienti con condizioni oculari preesistenti (miosi cronica da farmaci, glaucoma, ambliopia, retinopatia diabetica, precedente trapianto di cornea, precedente distacco di retina o iriti ecc.).

I chirurghi intenzionati ad impiantare una lente in questi pazienti dovrebbero considerare l'uso di m correzione della afachia alternativi e prevedere l'impianto di lente solo se le alternative sono rea insoddisfacenti ad incontrare i bisogni dei pazienti.

Alcune reazioni avverse che sono state associate all'impianto di lenti intraoculari in camera anteriore sono ri di seguito:

hypopion, scompensi corneali acuti, riposizionamento della lente, espianto della lente dovuto a contatto cornea o ad infiammazione, trapianto di cornea, infezione intraoculare, sostituzione della lente, aspirazi vitreo per blocco pupillare, iridectomia per blocco pupillare.

Gli effetti a lungo termine dell'impianto di lenti intraoculari non sono stati determinati. Perciò, i chirurghi dovr continuare a monitorare l'impianto dei pazienti nel post-operatorio con regolarità .

I chirurghi che prevedono l'impianto di lente in pazienti con degenerazione retinica o maculare senile dovr essere consapevoli che il paziente potrebbe non ottenere alcun vantaggio nell'acuità visiva centrale susse all'impianto della lente.

Pazienti con patologie oculari quali glaucoma o malattie corneali, potrebbero non ottenere l'acuità visi pazienti senza tali problemi.

Forme di glaucoma secondario sono state occasionalmente riportate in pazienti con glaucoma controlla hanno ricevuto impianti di lente in camera posteriore.

La pressione intraoculare in pazienti con impianto soggetti a patologie oculari dovrebbero essere attenta monitorati nel post-operatorio.

Ipoema, edema maculare e vitriti sono state riportate in pazienti che hanno manifestato complicanze chiru associate alla procedura di estrazione della cataratta (rottura della capsula posteriore, distacco della mem di Descemet, sanguinamento della camera anteriore, danni iridei, spinta vitreale o perdita di vitreo).

Pazienti che hanno manifestato complicanze operatorie dovrebbero essere monitorati attentamente nel operatorio per lo sviluppo di queste complicanze.

La sicurezza e l'efficacia di una lente da camera posteriore, se posizionata in camera anteriore, non è stabilita. L'impianto di lenti da camera posteriore in camera anteriore non si è dimostrata in alcuni casi sic

Il bisogno di una iridectomia secondaria in caso di blocco pupillare può essere prevenuto da una o più iridec al momento dell'impianto della lente intraoculare.

L'efficacia delle lenti intraoculari con filtraggio U.V. nella riduzione dell'incidenza dei disordini della retina r stata stabilita.

Alcune lenti intraoculari Storz sono state prodotte con ottiche dal diametro di 5 mm. Piccoli decentramenti d lente intraoculare con piccola e ristretta ottica possono dare come risultato in alcuni pazienti abbagliame altri disturbi visivi sotto certe condizioni di illuminazione.

I chirurghi dovrebbero considerare questo potenziale rischio prima di impiantare una lente intraoculare ottica piccola e ristretta.

Principal Investigator
Last

Lens Model #

Lens Control #

"視導" 人工
衛署醫器輸
藥商: 寶敦企業股份有限公司
地址: 台北市建國北路 1 段 96
有效日期及製造批號請見外盒

※外文仿單應檢附中文譯本

仿單標籤

產品名稱 "視準"人工水晶体眼鏡

衛生署給證號碼 衛署醫器輸

88. 8. 11

Stor

PRECAUZIONI

1. Non cercare di risterilizzare questa lente
2. Non conservare la lente alla diretta esposizione della luce solare o a temperature superiori ai 40°C. Non conservare in frigorifero.
3. Non lavare o risciaquare la lente in soluzioni che non siano soluzione salina bilanciata o similari. 4. Un alto livello di pratica chirurgica è richiesto per l'impianto di una lente intraoculare. Il chirurgo dovrebbe avere osservato e/o assistito a numerosi interventi di impianto e aver completato uno o più corsi di impianto di lente intraoculare prima di cercare di impiantare lenti intraoculari
5. Non usare se la busta sterile è aperta o danneggiata
6. Il paziente deve essere avvertito che il dottore o il centro medico dovrebbero essere stati informati circa gli effetti collaterali non riferiti alle informazioni ricevute dal paziente prima della chirurgia.

COME VIENE FORNITO

Le lenti intraoculari Storz sono fornite STERILI in una confezione asciutta, sigillata a caldo.
La confezione interna è sterilizzata in fase terminale e deve essere aperta soltanto sotto condizioni sterili.

MODALITA' D'USO

- Per rimuovere la lente: aprire la busta esterna e rimuovere il contenitore in un ambiente sterile.
- Se il contenitore è trasparente: Sollevare con attenzione lo sportello del contenitore per rimuovere la lente. Se il contenitore è grigio: Spingere indietro lo sportello del contenitore per rimuovere la lente.
- Rimuovere la lente, afferrando l'ottica con le banche delle pinze da impianto, e sollevarla dal contenitore. Si consiglia di non usare altre pinze o portaghi.
- Non lavare o risciaquare la lente in soluzioni che non siano soluzione salina bilanciata o similari
- La lente dovrebbe essere attentamente controllata per assicurarsi che non ci siano particelle aderenti sulla sua superficie.
- Le lenti monopezzo in PMMA della Storz sono disegnate per essere compresse soltanto sul piano della lente stessa. Per evitare rotture, non cercare di espandere le anse, fletterle fuori dal piano della lente o torcere la lente.
- Prima dell'impianto esaminare la lente per verificare il tipo, il potere diottrico, la configurazione e le superfici ottiche.

LENTES INTRAOCULARES CON FILTRO UV PARA CAMARA ANTERIOR Y POSTERIOR STORZ

DESCRIPCION DE PRODUCTO E INDICACIONES

Las lentes intraoculares Storz con filtro UV para cámara anterior y posterior, fabricadas por Storz (
Inc., son implantes ópticos para la sustitución del cristalino humano. Las lentes intraoculares Storz est
para implantación primaria en la corrección visual de la afaquia en pacientes de 60 ó más años de ed
se retira el cristalino con catarata.

Las lentes de cámara posterior están indicadas tras la extracción de cataratas por métodos d
extracapsular. Las lentes de cámara anterior están indicadas tras la extracción primaria de la catarata
intra o extracapsular o después de una intervención previa que requiera una procedimiento de i
secundaria.

Las lentes intraoculares Storz están fabricadas con polimetilmetacrilato (PMMA) al que se añade un
absorbente de rayos UV.

Las lentes están disponibles en potencias (in situ) desde +4.0 hasta +34.0 dioptrías, en increme
dioptrías.

CONTRAINDICACIONES

Los pacientes con cualquiera de las siguientes afecciones pueden no ser candidatos adecuad
implantación de una lente intraocular dado que la lente puede agravar la enfermedad preexistente, in
el tratamiento de la misma o suponer un riesgo excesivo para la visión del paciente : cataratas bilaterales
pacientes con inflamación recurrente del segmento posterior o anterior de etiología desconocida; pa
ojos que tengan el segmento anterior reducido, por ejemplo, microftalmos o ciertas formas de glauco
de ángulo cerrado; para implantación de cámara anterior, con historia previa o predisposición a despr
de retina; pacientes en los que la lente intraocular pudiera obstaculizar la observación, diagnóstico o
de los trastornos del segmento posterior; dificultades quirúrgicas en el momento de la extracción de
que pudieran aumentar las complicaciones potenciales, por ejemplo, hemorragias persistentes, lesión
del iris, imposibilidad de eliminar el vítreo de la cámara anterior, presión positiva incontrolable, pérdida s
de vítreo o hemorragia importante de la cámara anterior; visión potencialmente buena en un solo ojo
incontrolable por medicamentos; distrofia endotelial corneal; retinopatía diabética proliferativa.

ADVERTENCIAS

Al igual que en todo procedimiento quirúrgico, la intervención implica ciertos riesgos. Entre las comp
potenciales que acompañan a la cirugía de cataratas o de implante se pueden incluir : desplazam
lente, precipitados no pigmentados, lesión endotelial corneal, hipertensión intraocular, infección (end
desprendimiento de retina, vitritis, edema macular cistoide, edema corneal, membranas pupilares, cám
plana, prolapso del iris, hipopión y glaucoma transitorio.

Principal Investigator
Last
Lens Model #
Lens Control #

"視準"人工
衛署醫器輸
廠商: 實教企業股份有限公司
地址: 台北市建國北路 1 段 96
有效日期及製造批號見外盒

仿單必須附中文譯本

衛 02011

仿單標籤粘貼

產品名稱	"視導"人工水晶体眼内	請廠商
衛生署給證號碼	衛署醫器輸	字第 (

88. 8. 11

Storz Ophtha

La seguridad de la implantación de lentes intraoculares no ha sido comprobada en pacientes con enfermedade oculares pre-existentes (miosis medicamentosa crónica, glaucoma, ambliopía, retinopatía diabética, trasplant previo de córnea, antecedente de desprendimiento de retina o iritis etc...) Antes de pensar en la implantación d una lente en dichos pacientes, el médico debería valorar el uso de métodos alternativos de corrección de l afaquia, y únicamente proceder a la implantación de la lente si las alternativas no fueran satisfactorias para la necesidades del paciente.

Algunas reacciones adversas asociadas con la implantación de lentes intraoculares de cámara anterior son hipopión, descompensación corneal aguda, reposicionamiento de la lente, extracción de la lente debido a contact corneal, extracción de la lente debido a inflamación, trasplante corneal, infección intraocular, recolocación de l lente, aspiración de vítreo o iridectomía por bloqueo pupilar.

No se ha determinado el efecto a largo plazo de la implantación de lentes intraoculares. Por ello, los médico deberían seguir controlando con regularidad, tras la intervención, a los pacientes implantados.

Antes de pensar en la implantación de una lente en pacientes con degeneración macular o retiniana senil, lo médicos deberían tener en cuenta que el paciente puede no obtener ninguna mejoría de la agudeza visual centra tras la implantación de la lente.

Los pacientes con patología ocular, por ejemplo glaucoma ó enfermedades de la córnea, pueden no alcanzar l misma agudeza visual los pacientes que no presenten tales problemas. Ocasionalmente, se ha observad glaucoma secundario en pacientes con glaucoma controlado a los que se ha implantado una lente de cámar posterior. La presión intraocular de los pacientes con patología ocular a los que se implanta una lente, debe se controlada cuidadosamente tras la intervención.

Se ha registrado hipema, edema macular y vitritis en pacientes con complicaciones quirúrgicas asociadas a l extracción de cataratas (rotura de la cápsula posterior, desprendimiento de la membrana de Descemet, hemorrag de la cámara anterior, lesiones en el iris y engrosamiento o pérdida de vítreo).

Los pacientes que presenten complicaciones quirúrgicas deben ser cuidadosamente controlados durante l postoperatorio para evitar dichas complicaciones.

La seguridad y eficacia de una lente de cámara posterior, si se implanta en cámara anterior, no ha sido todavi establecida. En algunos casos se ha demostrado que la implantación de lentes intraoculares de cámara poster en cámara anterior no es segura.

La necesidad de practicar una iridectomía secundaria por obstrucción pupilar puede evitarse mediante una más iridectomías, en el momento de la implantación de la lente.

La eficacia de las lentes intraoculares con filtro absorbente UV en la reducción de la incidencia de trastorno retinianos no ha sido establecida.

Algunas lentes intraoculares Storz son fabricadas con ópticas de 5.00 mm. Los pocos casos de descentració de la lente que se dan con lentes intraoculares de óptica pequeña o estrecha podrían provocar en el pacient deslumbramientos u otros trastornos visuales bajo ciertas condiciones de luminosidad. Los cirujanos deberí tener en cuenta esta posibilidad antes de implantar una lente intraocular con óptica pequeña o estrecha.

PRECAUCIONES

1. No reesterilizar la lente.
2. No almacenar la lente en contacto directo con la luz o a temperaturas superiores a 40°C. No refrigerar.
3. No sumergir o lavar las lentes en soluciones distintas a solución salina compensada o equivalente.
4. Para la implantación de lentes intraoculares, se requiere un alto nivel de experiencia. Antes de proceder a la implantación de lentes intraoculares, el cirujano debería haber observado y haber asistido a numerosas implantaciones quirúrgicas y haber completado uno o más cursos sobre implantación de lentes intraoculares.
5. No utilizar si el envase estéril ha sido abierto o dañado. Debe advertirse al paciente de la necesidad de informar al doctor o centro médico sobre cualquier efecto colateral no mencionado en la información que el paciente recibe antes de la intervención.

FORMA DE PRESENTACION

Las lentes intraoculares Storz se suministran estériles y secas en un envase termosellado. El envase interno está esterilizado y debería abrirse únicamente bajo condiciones estériles.

INSTRUCCIONES DE USO

- Para retirar la lente, abrir el envase externo y retirar la bandeja en un ambiente estéril.
- Cuidadosamente, levantar la cubierta (bandeja transparente) o desplazarla hacia atrás (bandeja gris) para dejar expuesta la lente.
- Retirar la lente sujetándo la óptica con unas pinzas atraumáticas y tirar hacia arriba. No deben utilizarse nunca pinzas con cierre portagujas.
- No sumergir o lavar la lente con otras soluciones distintas a la solución salina compensada o equivalentes.
- Examinar cuidadosamente la lente para asegurar que no tiene partículas adheridas.
- Las lentes de PMMA de una sola pieza Storz han sido diseñadas únicamente para compresión en el plano de la lente. Para evitar roturas, no se debe intentar estirar las hápticas, flexionarlas en un plano distinto al de la lente, ni girar o retorcer la lente.
- Antes de la implantación, comprobar el tipo, potencia, configuración y superficie óptica de la lente.

Principal Investigator
Last

Lens Model #

Lens Control #

"視導" 人工
衛署醫器輸
藥商: 寶放企業股份有限公司
地址: 台北市建國北路 1 段 96 號
有效日期及製造批號請見外盒

※外文仿單應檢附中文譯本

Storz Ophthalmics, Inc.
21 Park Place Boulevard North
Clearwater, Florida 33759
USA

Europe:
Storz Instrument GmbH
Im Schuhmachergewann 4
D-69123 Heidelberg, Germany

Storz Ophthalmics' sincere commitment to ophthal-
mology brings to you the finest quality intraocular
for implantation in the human eye.

LVD. N.
33759

14088 J

storz®
STORZ OPHTHALMICS, INC.

R LENS

GE
ICULAIRE
LARE
LAR

ISTRIBUTION

O

14835C

視導" 人工水晶體眼球
醫器輸字第 009172 號
商: 賽敦企業股份有限公司
址: 台北市建國北路 1 段 96
效日期及製造批號請見外盒

0013645

Printed on Recycled Paper

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 331 CLEARWATER FL
POSTAGE WILL BE PAID BY ADDRESSEE

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

REGULATORY AFFAIRS
STORZ OPHTHALMICS INC
21 PARK PLACE BLVD N
CLEARWATER FL 33759-9881

衛 02011

仿單標籤粘貼表

產品名稱	視導"人工水晶体眼内植	申請廠商	博士倫股份有限公司
衛生署給證號碼	衛署醫器輸	字第 009172	號

88. 8. 11

88. 8. 11

Storz Ophthalmics' sincere commitment to ophthalmology brings to you the finest quality intraocular lenses available for implantation in the human eye.

21 PARK PLACE BLVD. N.
CLEARWATER, FL 33759
(813) 724-6600
7/97

14088 J

storz®
STORZ OPHTHALMICS, INC.

STORZ OPHTHALMICS, INC.

According to Federal (USA) regulations, this form must be completed and returned to Storz Ophthalmics, Inc. for all lenses implanted, lost, or destroyed.

Patient Name
Last
First M.I.

Patient S.S. No. - -

Date of Birth Month Day Year

Hospital Name

Hospital Address State

Surgeon Name
Last F.I. M.I.

Date of Surgery Month Day Year

OD OS

Anterior Chamber ☐
Posterior Chamber ☐
Primary Implantation ☐
Secondary Implantation ☐

Principal Investigator
Last F.I. M.I.

14891B

Lens Model #

Lens Control #

ATTACH STICKER HERE

"視導" 人工

衛署醫器輸

藥商: 寶敦企業股份有限公司

地址: 台北市建國北路 1 段 96 [illegible]

有效日期及製造批號請見外盒

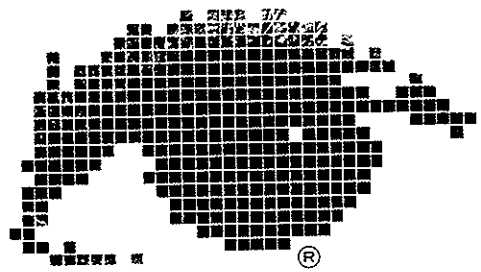
7/97

※外文仿單應檢附中文譯本

0013645

storz®
OPHTHALMICS

Intraocular Lens



INTRAOKULARLINSE
LENTILLE INTRA-OCULAIRE
LENTE INTRAOCULARE
LENTE INTRAOCULAR

T° < 43°C / 110°F

storz®
OPHTHALMICS

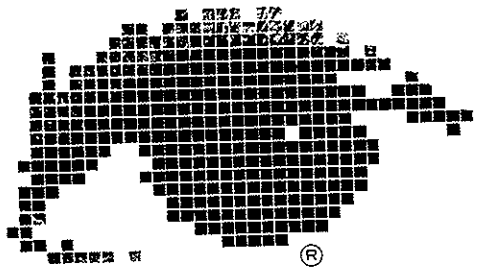
Do not store the lens in direct sunlight or at temperatures higher than 43°C/110°F

storz®
OPHTHALMICS

storz®
OPHTHALMICS

EZE-FIT®
Intraocular Lens

Equiconvex Optic
One-Piece PMMA
Flexible Haptics



INTRAOKULARLINSE
LENTILLE INTRA-OCULAIRE
LENTE INTRAOCULARE
LENTE INTRAOCULAR

T° < 43°C / 110°F

storz®
OPHTHALMICS

Do not store the lens in direct sunlight or at temperatures higher than 43°C/110°F

5. 不可使用已破損或開啟…
6. 手術前醫師需告…

…簽以粘貼全型實物為原則。
…本或印於玻璃金屬容器等不便於
…黏本代替粘貼報核。

storz®

storz®
OPHTHALMICS

storz®
OPHTHALMICS

BLUE VISTA®
Intraocular Lens

Equiconvex Optic
One-Piece PMMA
With Blue Haptics

INTRAOKULARLINSE
LENTILLE INTRA-OCULAIRE
LENTE INTRAOCULARE
LENTE INTRAOCULAR

T° < 43°C / 110°F

storz®
OPHTHALMICS

Do not store the lens in direct sunlight or at temperatures higher than 43°C/110°F

FOR INTER…

CE 0125 ST…

"視導"…
衛署醫器…
藥商：寶…
地址：台北市…
有效日期及製造批號…見外盒

…文譯本

0013645

STORZ OPHTHALMICS

STORZ Ophthalmics, Inc.
21 Park Place Boulevard North
Clearwater, Florida 33759
USA

Europe:
STORZ Instrument GmbH
Im Schuhmachergewann 4
D-69123 Heidelberg, Germany

nent GmbH
ıergewann 4
ılberg, Germany

ıackage has
ɔrmation.

ıent GmbH
ergewann 4
berg, Germany

ackage has
ırmation.

Contents: One intraocular lens. Sterile unless enclosed package has been opened or damaged. See insert for professional information.

CE 0125 STERILE EO

14810C 14766E

14049N

4/97

應避免瞳孔的二次虹膜切開。

防止紫外線的晶體無法減少視網膜移位的發生率。

少數晶體偏心，發生小或狹窄視力，使病人在這種光線下產生閃爍或其他視覺障礙，醫師在植入前，需事先考量。

警告：

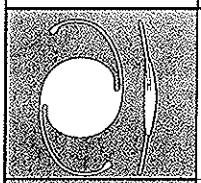
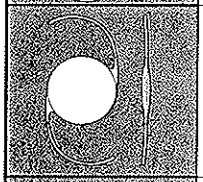
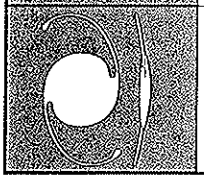
1. 不可重覆消毒使用。
2. 不要直接儲存在日光照射或超過 40°C。
3. 不要用非等張平衡鹽類的溶液清洗。
4. 植入人工水晶體需具備純熟的手術技術。

BLUE VISTA®

Blue Vista® lenses combine the benefits of STORZ' conventional one-piece lens design with the enhanced haptic visibility from traditional three-piece lens models.

Blue Vista:

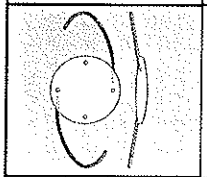
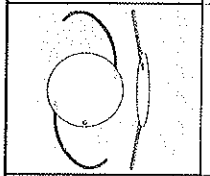
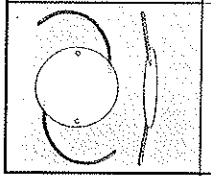
Feature:	*Benefit:*
-High Molecular Weight PMMA	-Yag Compatible
-Blue Haptic	-Easier Visibility
-PMMA Haptic	-More Durable than Polypropylene
	-Added Stability
-Equiconvex Optic	-Full Aperture Refractive Surface
	-Stable Optical A-Constant Plane
	-1:1 Anterior-to-Posterior Curvature Ratio
	-Thinnest Possible Optic Design.

LENS DESIGN	*MODEL NUMBER*	*OPTIC DESIGN*	*OPTIC SIZE (mm)*	*POSITIONING HOLES 0.34mm STANDARD*	*LENGTH (mm)*	*EFFECTIVE HAPTIC ANGLE*	*HAPTIC DESIGN*	*"A" CONSTANT AC DEPTH*	*UV ABSORBING*	*OTHER FEATURES*
	95BUV	EQUICONVEX	7.0	0	13.75	10°	MODIFIED C	118.0 4.96mm	YES	BLUE HAPTICS
	BV359	EQUICONVEX	5.5	0	12.25	DOUBLE FLAT STEP-VAULTED 2.4°	MODIFIED C	118.0 4.96mm	YES	BLUE HAPTICS
	P325BUV	EQUICONVEX	6.5	0	13.75	10°	MODIFIED C	118.0 4.96mm	YES	BLUE HAPTICS

storz®
OPHTHALMICS

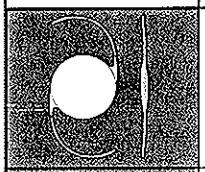
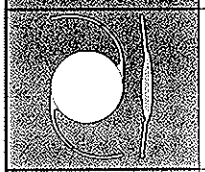
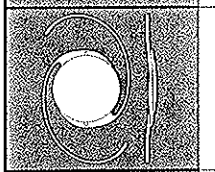
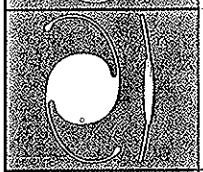
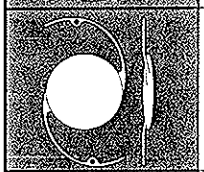
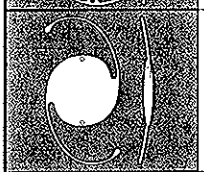
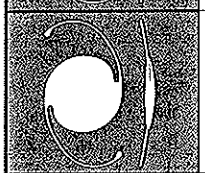
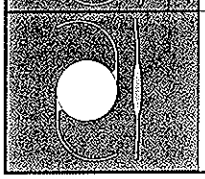
ASSEMBLED POLYPROPYLENE – PMMA

Three-Piece Polypropylene

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH	UV ABSORBING	OTHER FEATURES
	71UV	BICONVEX	6.0	4	13.75	10°	MODIFIED J POLYPROPYLENE	119.0 5.55mm	YES	
	P013UV	EQUICONVEX	6.5	1	14.00	10°	MODIFIED J POLYPROPYLENE	118.5 5.26mm	YES	
	127UV	EQUICONVEX	7.0	2	13.75	10°	MODIFIED C POLYPROPYLENE	118.0 4.96mm	YES	

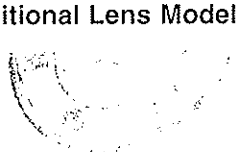
STORZ® OPHTHALMICS

ONE-PIECE DESIGNS

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH	UV ABSORBING	OTHER FEATURES
	P359UV	EQUICONVEX	5.5	0	12.25	DOUBLE FLAT STEP-VAULTED 2.4°	MODIFIED C	118.0 4.96mm	YES	MULTI-DIRECTIONAL FLEXIBILITY HAPTIC AVAILABLE IN EXTENDED HIGH DIOPTER POWERS
	P379UV	EQUICONVEX	6.0	0	13.00	STEP-VAULTED 6.5°	MODIFIED C	118.4 5.20mm	YES	MULTI-DIRECTIONAL FLEXIBILITY
	68UV	BICONVEX	6.0	2	13.75	STEP-VAULTED 5.9°	MODIFIED C	118.5 5.26mm	YES	AVAILABLE IN EXTENDED LOW DIOPTER POWERS
	P010UV	EQUICONVEX	6.5	1	13.75	10°	MODIFIED C	118.0 4.96mm	YES	MULTI-DIRECTIONAL FLEXIBILITY
	P366UV	EQUICONVEX	6.5	0	13.4 12.0 EYELET TO EYELET	STEP-VAULTED 6.6°	MODIFIED C	118.5 5.26mm	YES	MULTI-DIRECTIONAL FLEXIBILITY EYELET ON HAPTICS (.43MM)
	P525UV	EQUICONVEX	6.5	2	13.75	10°	MODIFIED C	118.0 4.96mm	YES	MULTI-DIRECTIONAL FLEXIBILITY
	95UV	EQUICONVEX	7.0	0	13.75	10°	MODIFIED C	118.0 4.96mm	YES	MULTI-DIRECTIONAL FLEXIBILITY
	P389UV	EQUICONVEX	5.5	0	13.00	DOUBLE FLAT STEP-VAULTED 2.1°	MODIFIED C	118.0 4.96mm	YES	MULTI-DIRECTIONAL FLEXIBILITY

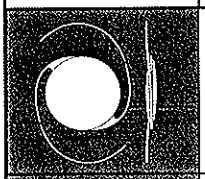
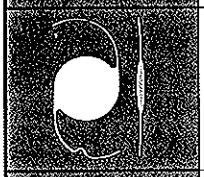
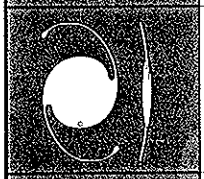
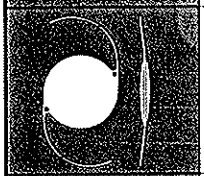
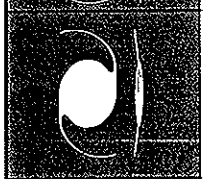
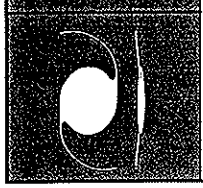
Additional Lens Models on back of page



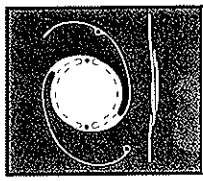


storz® OPHTHALMICS

ONE-PIECE DESIGNS

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH	UV ABSORBING	OTHER FEATURES
	P351UV	EQUICONVEX	6.5	0	12.50	STEP-VAULTED 7.6°	MODIFIED C	118.5 5.26mm	YES	MULTI-DIRECTIONAL FLEXIBILITY
	P399UV	EQUICONVEX	5.5	0	12.25	DOUBLE FLAT STEP-VAULTED 2.4°	MODIFIED C	118.0 4.96mm	YES	MULTI-DIRECTIONAL FLEXIBILITY NOTCH ON HAPTIC
	P484UV	EQUICONVEX	6.5	1	13.00	10°	MODIFIED C	117.9 4.91mm	YES	MULTI-DIRECTIONAL FLEXIBILITY
	P563UV	EQUICONVEX	6.5	2	13.50	STEP-VAULTED 6.0°	MODIFIED C	118.4 5.20mm	YES	MULTI-DIRECTIONAL FLEXIBILITY
	P329UV	EQUICONVEX	5.0 X 6.0	0	12.00	STEP-VAULTED 7.6°	MODIFIED C	118.4 5.20mm	YES	MULTI-DIRECTIONAL FLEXIBILITY
	P337UV	EQUICONVEX	5.0 X 6.0	0	13.00	STEP-VAULTED 6.5°	MODIFIED C	118.4 5.20mm	YES	MULTI-DIRECTIONAL FLEXIBILITY

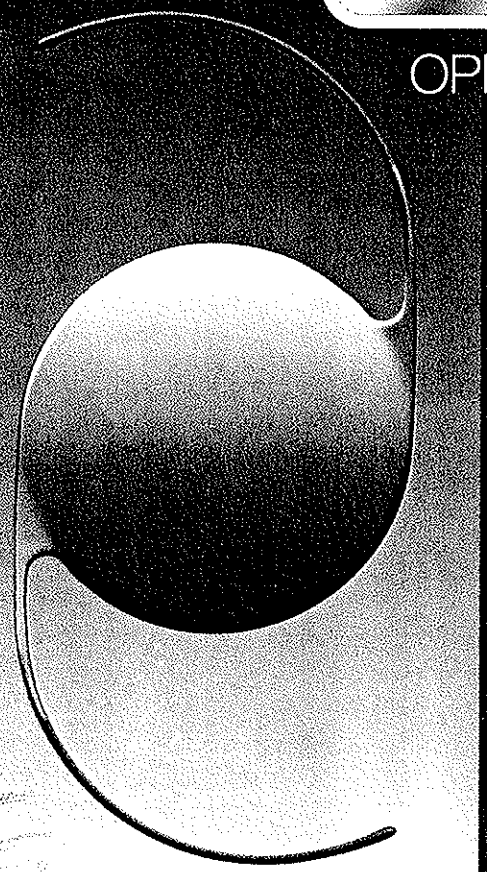
Laser Ridge

	68RUV	BICONVEX	6.5 X 7.0	2	13.75	STEP-VAULTED 6.3°	MODIFIED C	117.3 4.56mm	YES	RIDGED OPTIC EYELET ON HAPTIC WITH CONTROL TIP

storz OPHTHALMICS

BEOPZ®

OPHTHALMICS



INTRA-OCULAR LENSES

CATALOG

FEATURING

THE EZE-FIT™ IOL

EXTENDED
RANGE DIOPTER
POWERED INTRAOCULAR LENSES

&

BLUEVISTA®
INTRAOCULAR LENSES

OPHTHALMICS

DIOPTRIC POWER RANGES

Many IOL designs from STORZ Ophthalmics are available from +10.0 to +30.0 D in .5 D steps. Most designs are available from +14.0 to +27.0 D in .5 D steps.

Extended Range Powers available from -18.0 D to +45.0 D on selected models. See page 15 for more information.

"A" CONSTANTS AND AC DEPTHS

The suggested "A" Constants and estimated AC Depths listed in this catalog are presented as guidelines only. It is recommended that personalized "A" Constants and AC Depths be developed based on individual experience with an implant design, surgical technique, measuring equipment and postoperative results.

RETURN POLICY

STORZ Ophthalmics will accept all currently manufactured lenses for exchange only. Discontinued or special purchase lenses may not qualify for exchange.

Qualified lenses in the original unopened package may be returned and exchanged for another lens. Please call 1-800-325-9500 for a return authorization number.

CAUTIONS

All IOLs are limited by Federal (USA) law to sale by or on the order of a physician.

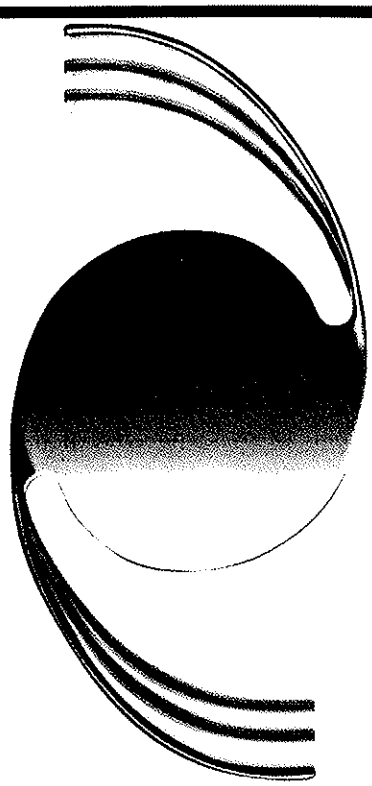
TRADEMARKS/PATENTS

EZE-FIT™ SYSTEM, BLUE VISTA®, CAPSULORBLUE™, STORZ®, and PHACO PROFILE®, are trademarks of STORZ Ophthalmics.

REGULATION POLICY

In order to comply with Medical Device Reporting (MDR) regulations, STORZ Ophthalmics has instituted a system to facilitate reporting of patient injury and malfunctions involving IOLs. All Events including particulate contamination, haptic breakage, and optic scratches due to damage, defect, or handling should be reported to STORZ Customer Service at 1-800-252-7890.

A NEW



THE EZE-FIT™ IOL SYSTEM

SERIES 0 ...Most flexible (comparable to assembled PMMA haptics)

SERIES 1 ...Intermediate flexibility

SERIES 2 ...Flexible (comparable to current one-piece PMMA haptics)

Each series maintains comparable flexibility of the haptics throughout the different optic sizes.

GENERATION OF ONE-PIECE PMMA LENSES

THE EZE-FIT™ IOL System

Features on all EZE-FIT™ Lenses

- *Equiconvex Full Aperture Refractive Surface*
- *Double flat, step-vaulted haptics*
- *High molecular weight material*

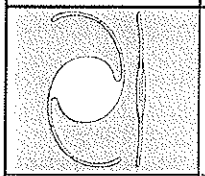
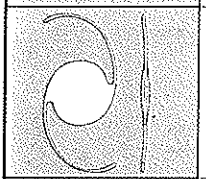
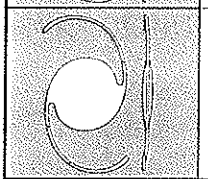
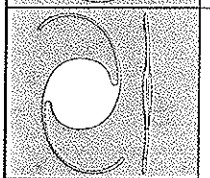
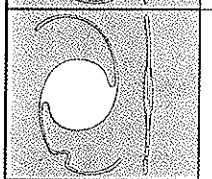
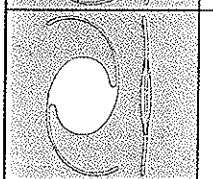
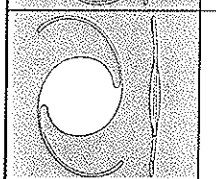
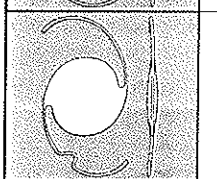
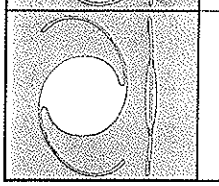
- The EZE-FIT™ IOL System is designed to accommodate any surgical technique.
- The comparable flexibility of haptics on different size optics within a series allows surgeons to change optic sizes without changing insertion technique.
- The model number describes the lens optic size and flexibility of the haptic.
- "A" Constant remains the same throughout the EZE-FIT™ IOL System allowing for no diopter change with different lenses.

OPTIC SIZE	SERIES 0	SERIES 1	SERIES 2
5.0mm	EZE-50 EZE-50S	EZE-150 EZE150A EZE-150S	P434UV P526UV P534UV P408UV
5.5mm	EZE-55 EZE-55N EZE-55S	EZE-155 EZE-155N EZE155A EZE-155S EZJ-155A	P359UV P399UV P499UV P389UV
5.0mm X 6.0mm	EZE-56		P328UV P329UV P336UV P337UV
6.0mm	EZE-60 EZE-60N	EZE-160 EZE-160N EZE160A EZJ-160A	P504UV P508UV P574UV
6.5mm	EZE-65	EZE-165 EZJ-165A	P517UV
7.0mm		EZJ-170A	

THE EZE-FIT™ IOL SYSTEM

SERIES 0 - *Most flexible haptic (comparable to assembled PMMA haptics)*

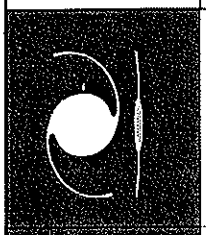
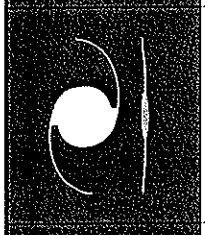
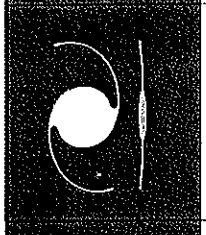
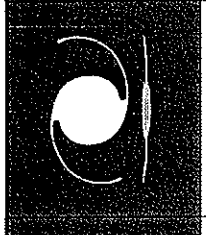
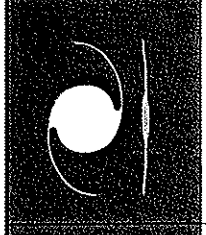
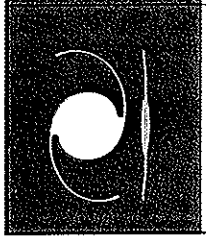
One-Piece PMMA Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	EZE-50S	EQUICONVEX	5.0	0	12.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-50	EQUICONVEX	5.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-55S	EQUICONVEX	5.5	0	12.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-55	EQUICONVEX	5.5	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-55N	EQUICONVEX	5.5	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH
	EZE-56	EQUICONVEX	5.0 X 6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-60	EQUICONVEX	6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-60N	EQUICONVEX	6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH
	EZE-65	EQUICONVEX	6.5	0	13.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	VERY FLEXIBLE MULTI-DIRECTIONAL HAPTIC

THE EZE-FIT™ IOL SYSTEM

SERIES 1 - *Intermediate haptic flexibility*

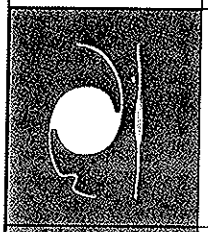
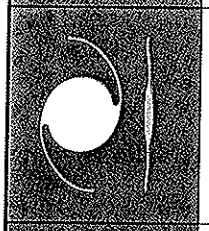
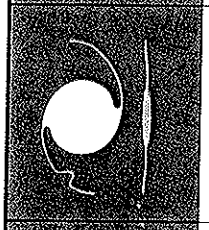
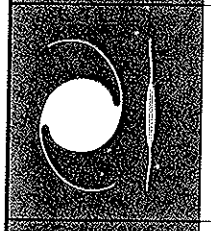
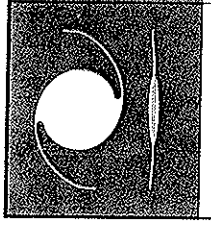
One-Piece PMMA Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	EZE-150S	EQUICONVEX	5.0	0	12.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-150	EQUICONVEX	5.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE150A	EQUICONVEX	5.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-155S	EQUICONVEX	5.5	0	12.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-155	EQUICONVEX	5.5	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE 155A	EQUICONVEX	5.5	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC

THE EZE-FIT™ IOL SYSTEM

SERIES 1 - *Intermediate haptic flexibility continued*

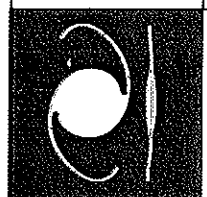
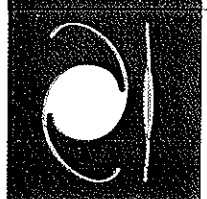
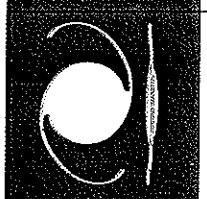
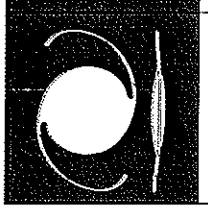
One-Piece PMMA Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	EZE-155N	EQUICONVEX	5.5	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH
	EZE-160	EQUICONVEX	6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-160N	EQUICONVEX	6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH
	EZE160A	EQUICONVEX	6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZE-165	EQUICONVEX	6.5	0	13.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC

THE EZE-FIT™ IOL SYSTEM

SERIES 1 - *Intermediate haptic flexibility continued*

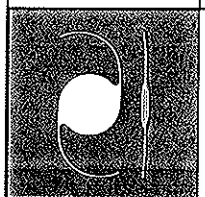
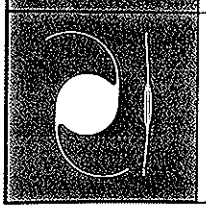
One-Piece PMMA Modified J Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	EZJ-155A	EQUICONVEX	5.5	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED J	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZJ-160A	EQUICONVEX	6.0	0	13.00	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED J	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZJ-165A	EQUICONVEX	6.5	0	13.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED J	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	EZJ-170A	EQUICONVEX	7.0	0	13.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED J	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC

THE EZE-FIT™ IOL SYSTEM

SERIES 2 - *Flexibility (comparable to current one-piece PMMA haptics)*

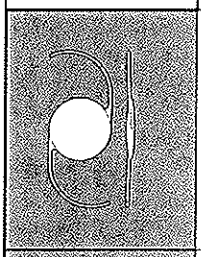
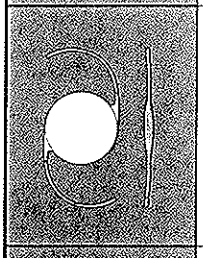
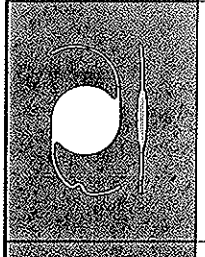
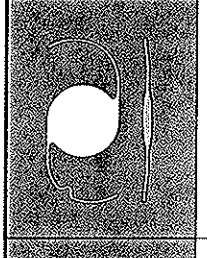
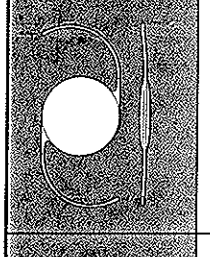
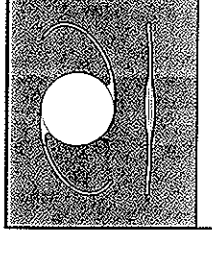
One-Piece PMMA Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	P434UV	EQUICONVEX	5.0	0	12.25	DOUBLE FLAT STEP-VAULTED 2.2°	MODIFIED C	118.0 4.96mm 1.22	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	P526UV	EQUICONVEX	5.0	0	12.75	STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC

THE EZE-FIT™ IOL SYSTEM

SERIES 2 - *Flexiblility (comparable to current one-piece PMMA haptics) continued*

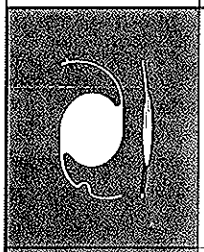
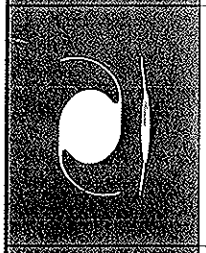
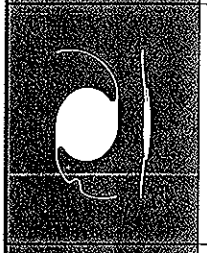
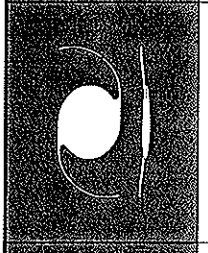
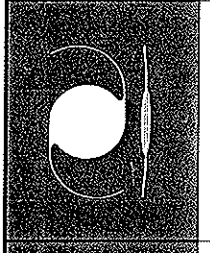
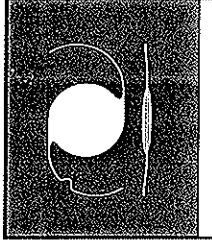
One-Piece PMMA Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	P408UV	EQUICONVEX	5.0	0	13.00	STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	P359UV	EQUICONVEX	5.5	0	12.25	DOUBLE FLAT STEP-VAULTED 2.4°	MODIFIED C	118.0 4.96mm 1.22	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC EXTENDED DIOPTER POWERS AVAILABLE PLANO TO + 45D
	P399UV	EQUICONVEX	5.5	0	12.25	DOUBLE FLAT STEP-VAULTED 2.4°	MODIFIED C	118.0 4.96mm 1.22	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH
	P499UV	EQUICONVEX	5.5	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH
	P389UV	EQUICONVEX	5.5	0	13.00	DOUBLE FLAT STEP-VAULTED 2.1°	MODIFIED C	118.0 4.96mm 1.22	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC EXTENDED DIOPTER POWERS AVAILABLE AS CUSTOM ORDER PLANO TO +45D
	P512UV	EQUICONVEX	5.5	0	13.25	DOUBLE FLAT STEP-VAULTED 2.5°	MODIFIED J	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC

THE EZE-FIT™ IOL SYSTEM

SERIES 2 - *Flexibility (comparable to current one-piece PMMA haptics) continued*

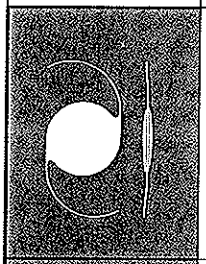
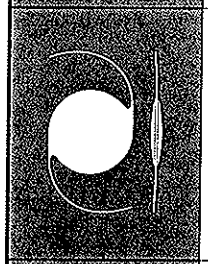
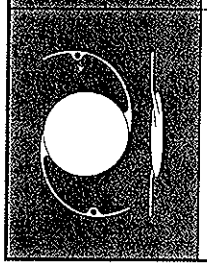
One-Piece PMMA Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	P328UV	EQUICONVEX	5.0 X 6.0	0	12.00	STEP-VAULTED 7.6°	MODIFIED C	118.4 5.20mm 1.45	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH
	P329UV	EQUICONVEX	5.0 X 6.0	0	12.00	STEP-VAULTED 7.6°	MODIFIED C	118.4 5.20mm 1.45	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	P336UV	EQUICONVEX	5.0 X 6.0	0	13.00	STEP-VAULTED 6.5°	MODIFIED C	118.4 5.20mm 1.45	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH
	P337UV	EQUICONVEX	5.0 X 6.0	0	13.00	STEP-VAULTED 6.5°	MODIFIED C	118.4 5.20mm 1.45	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	P504UV	EQUICONVEX	6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	P508UV	EQUICONVEX	6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC WITH NOTCH

THE EZE-FIT™ IOL SYSTEM

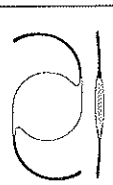
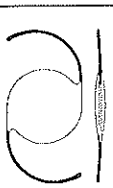
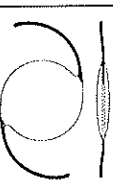
SERIES 2 - *Flexibility (comparable to current one-piece PMMA haptics) continued*

One-Piece PMMA Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	P574UV	EQUICONVEX	6.0	0	13.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC HIGH MINUS DIOPTER POWERS AVAILABLE -1 TO -18 WHOLE DIOPTER STEPS
	P517UV	EQUICONVEX	6.5	0	13.25	STEP-VAULTED 3°	MODIFIED C	118.0 4.96mm 1.22	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC HIGH MINUS DIOPTER POWERS AVAILABLE -1 TO -18 WHOLE DIOPTER STEPS CUSTOM ORDER
	P366UV	EQUICONVEX	6.5	0	13.4 12.0 EYELET TO EYELET	STEP-VAULTED 6.6°	MODIFIED C	118.5 5.26mm 1.51	YES	MULTI-DIRECTIONAL FLEXIBILITY EYELET ON HAPTICS

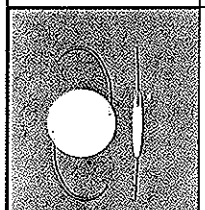
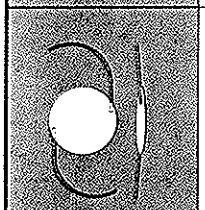
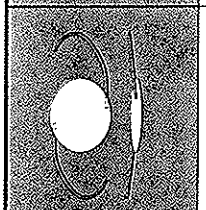
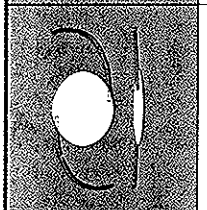
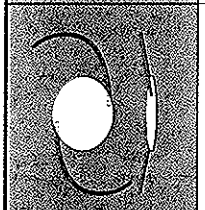
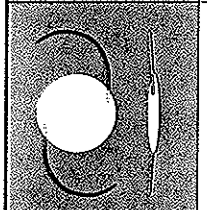
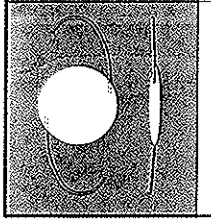
BLUE VISTA® IOLs

One-Piece Blue PMMA Haptic Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	BVR-150S	EQUICONVEX	5.0	0	12.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	BVR-150M	EQUICONVEX	5.0	0	12.75	DOUBLE FLAT STEP-VAULTED 2.9°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	BVR-155S	EQUICONVEX	5.5	0	12.25	DOUBLE FLAT STEP-VAULTED 3.1°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	BVR-155M	EQUICONVEX	5.5	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	BVR-160S	EQUICONVEX	6.0	0	12.25	DOUBLE FLAT STEP-VAULTED 2.9°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	BVR-160M	EQUICONVEX	6.0	0	12.75	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	BVR-165L	EQUICONVEX	6.5	0	13.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC
	BVR-170L	EQUICONVEX	7.0	0	13.25	DOUBLE FLAT STEP-VAULTED 3°	MODIFIED C	118.1 5.02mm 1.28	YES	FLEXIBLE MULTI-DIRECTIONAL HAPTIC

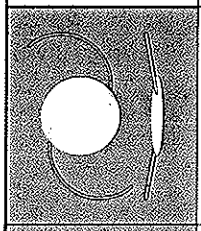
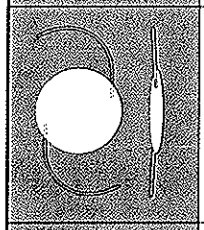
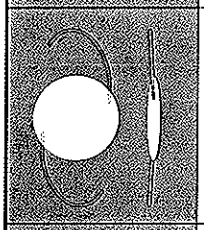
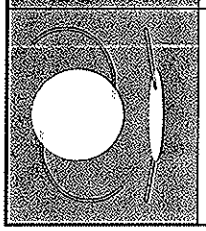
CAPSULORBLUE™ IOLs

Assembled Blue PMMA Haptic Posterior Chamber Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	P519UV	EQUICONVEX	5.5	0	12.50	3°	MODIFIED J ASSEMBLED PMMA	117.9 4.91mm 1.17	YES	
	P454UV	EQUICONVEX	5.5	0	12.75	4°	MODIFIED C ASSEMBLED PMMA	118.0 4.96mm 1.22	YES	
	P541UV	EQUICONVEX	5.0 X 6.0	0	13.50	7°	MODIFIED J ASSEMBLED PMMA	118.4 5.20mm 1.45	YES	
	P391UV	EQUICONVEX	5.0 X 6.0	0	13.25	3°	MODIFIED C ASSEMBLED PMMA	118.0 4.96mm 1.22	YES	
	560CUV	EQUICONVEX	5.0 X 6.0	0	13.75	10°	MODIFIED C ASSEMBLED PMMA	118.5 5.26mm 1.51	YES	
	P453UV	EQUICONVEX	6.0	0	12.75	4°	MODIFIED C ASSEMBLED PMMA	118.0 4.96mm 1.22	YES	
	P524UV	EQUICONVEX	6.0	0	13.50	3°	MODIFIED J ASSEMBLED PMMA	117.9 4.91mm 1.17	YES	

CAPSULORBLUE™ IOLs continued

Assembled Blue PMMA Haptic Posterior Chamber Lenses

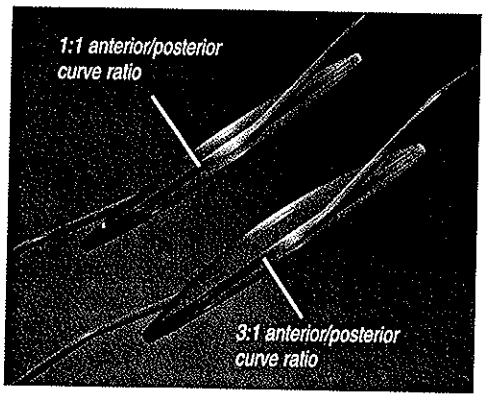
LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	P506UV	EQUICONVEX	6.0	0	13.50	10°	MODIFIED C ASSEMBLED PMMA	118.5 5.26mm 1.51	YES	
	P518UV	EQUICONVEX	6.5	0	13.25	4°	MODIFIED C ASSEMBLED PMMA	118.0 4.96mm 1.22	YES	
	P538UV	EQUICONVEX	6.5	0	13.50	3°	MODIFIED J ASSEMBLED PMMA	117.9 4.91mm 1.17	YES	
	P507UV	EQUICONVEX	7.0	0	13.50	10°	MODIFIED C ASSEMBLED PMMA	118.0 4.96mm 1.22	YES	

ANTERIOR CHAMBER IOLs

One-Piece PMMA AC Lenses

LENS DESIGN	MODEL NUMBER	OPTIC DESIGN	OPTIC SIZE (mm)	POSITIONING HOLES 0.34mm STANDARD	LENGTH (mm)	EFFECTIVE HAPTIC ANGLE	HAPTIC DESIGN	"A" CONSTANT AC DEPTH "S" FACTOR	UV ABSORBING	OTHER FEATURES
	S122UV	EQUICONVEX	6.0	0	12.50	STEP-VAULTED 4.4°	MODIFIED S	115.8 3.68mm -0.022	YES	4PT FIXATION
	L122UV	EQUICONVEX	6.0	0	13.75	STEP-VAULTED 3.7°	MODIFIED S	115.8 3.68mm -0.022	YES	4PT FIXATION

STORZ Equiconvex IOLs – *Shaped for Success*



STORZ equiconvex optics vs. "standard" biconvex optic. Both 1:1 and 3:1 ratios provide good optical performance; however, only a 1:1 ratio permits a perfectly balanced, thin lens design.

1:1 Anterior-to-Posterior Curvature Ratio

- Outstanding optical performance – less spherical aberration than conventional IOLs.[1]
- Minimal image degradation due to decentration or tilt; minimal internal reflection.[1]

Stable Optical Planes

- Principal plane designed for minimal detectable shift – regardless of power.

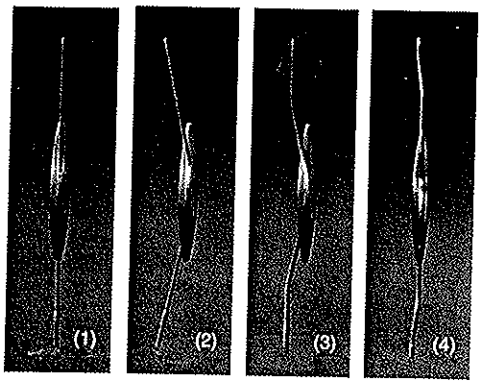
Equiconvex Profile Permits Thinnest Possible Designs

- Thin edges designed to minimize edge glare.
- Low lens mass facilitates implantation.

Maintains Posterior Capsule Contact

- Enhances YAG compatibility, fewer shots required to open posterior capsule.[2]

STORZ Step-Vaulted IOLs – *Secure Placement by Design*



(1) Planar (0°) angulation does not position optic away from iris or anterior capsule;

(2) 10° angulation holds lens against posterior capsule, but may sacrifice stability;

(3) Step-vaulted haptics are designed to achieve maximum stability and facilitate implantation, but increase pressure on posterior capsule;

(4) Double flat, step-vaulted haptics offer a unique solution.

Step-Vaulted Haptic Balances Flexibility with Stability

- High quality one-piece PMMA lens permits easy insertion into the bag.

Facilitates In-The-Bag Implantation

- Flat end of haptic prevents skating over the viscoelastic.[2]

Stress is Distributed Evenly Along Flat Portion of Haptic

- Step vaulting is designed to assure stability in the bag.

Step-Vaulted Design Conforms to the Anatomy of the Eye

- Haptic is initially angled upward, then flattened.
- Controlled flexibility.

Designed for Controlled Vault to Minimize Tilt and Decentration

- Flattened portion of haptic rests in fornix of capsule to stabilize lens.

Holds IOL Gently Against Posterior Capsule

- Stretches posterior capsule smoothly across optic surface.

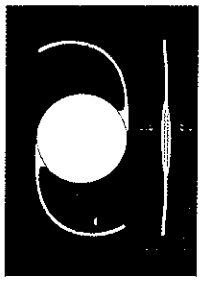
Double Flat, Step Vaulted Design Offers These Features:

- Ease of insertion of a planar design.
- The benefits of an angled design.
- The stability of a step-vaulted design.

References:
1. Holladay JT. Evaluating the intraocular lens optic. *Surv Ophthalmol.* 1986;30:385-390.
2. Data on file, Storz Ophthalmics, St. Louis, Mo.

Extended Diopter Range Lenses From STORZ

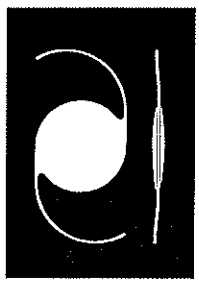
P359UV



Diopter range available
Plano to +45D. half
diopter steps

Optic Size: 5.5mm
Overall Length: 12.25mm
A-Constant: 118.0

P574UV



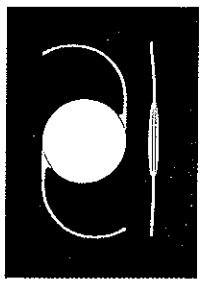
Diopter range available
-1D. to -18D. in whole
diopter steps

Optic Size: 6.0mm
Overall Length: 13.25mm
A-Constant: 118.1

Extended Diopter Range Lenses are not available for consignment. Storz will stock the above IOL models in the extended range for immediate delivery. It is recommended that IOLs are ordered before scheduling surgery.

The Following Two IOL Models can be Custom Ordered in Extended Diopter Range

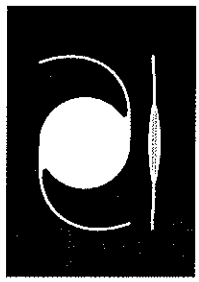
P389UV



Diopter range available
Plano to +45D. half
diopter steps

Optic Size: 5.5mm
Overall Length: 13.00mm
A-Constant: 118.0

P517UV

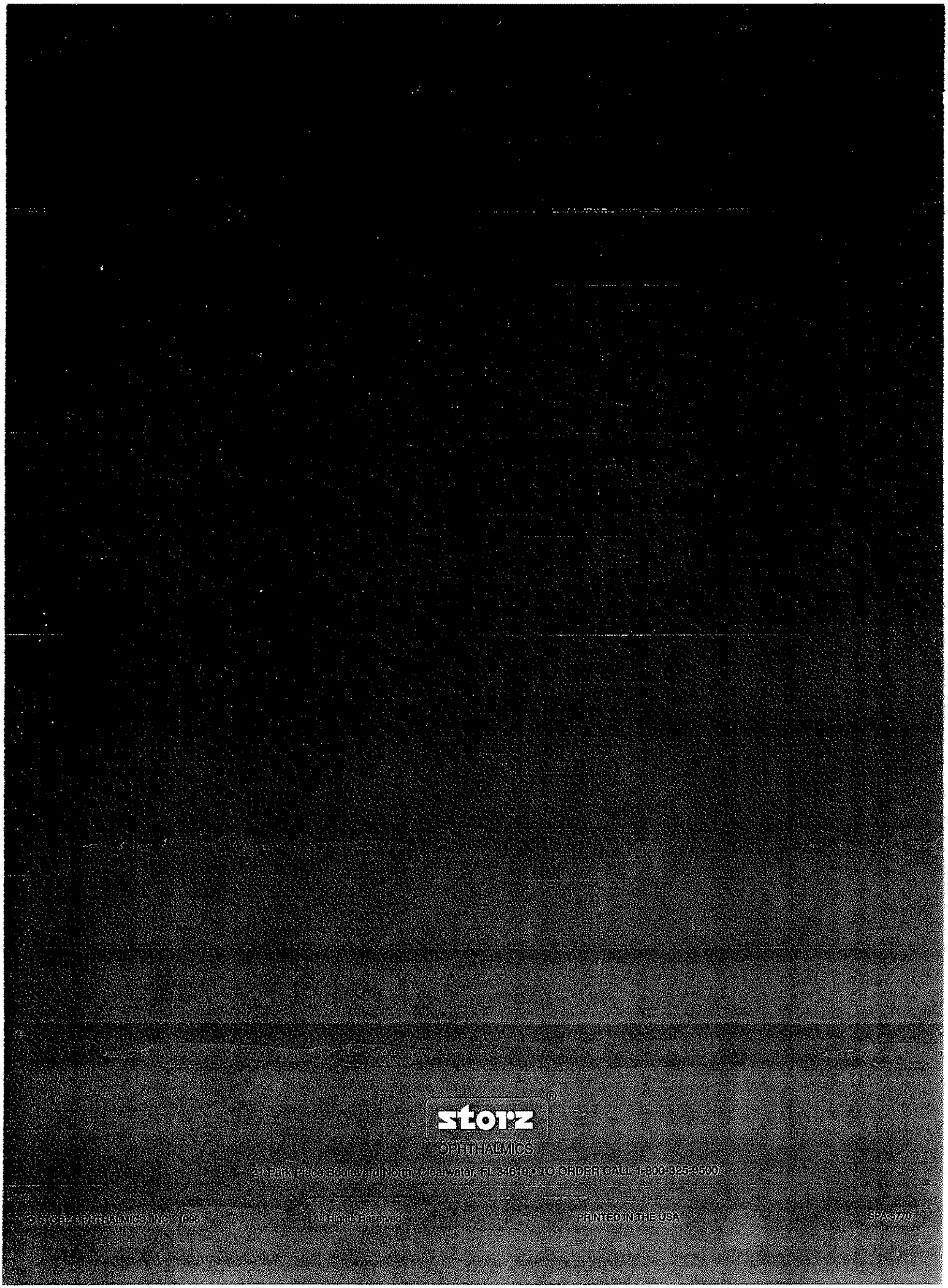


Diopter range available
-1D. to -18D. in whole
diopter steps

Optic Size: 6.5mm
Overall Length: 13.25mm
A-Constant: 118.0

The above IOL models can be custom manufactured with an expected delivery date of 45 days from the date of order.

For more information on extended diopter range IOLs from Storz contact your Storz Sales Representative or call Customer Service at 1-800-325-9500.



storz®
OPHTHALMICS

2150 Park Place Boulevard North, Clearwater, FL 34619 • TO ORDER CALL 1-800-325-3500

PRINTED IN THE USA SPA-5740

68UV **storz** +04.0
Posterior Chamber IOL
SN: x00101 Length:13.75
Optic Size: 6.00mm Haptic angulation: Step-vaulted
Optic Design: Biconvex
Haptic Design:
Short C
Placement: Ciliary sulcus or capsular bag
Material:
PMMA with UV absorber

storz Model 68UV
Length 13.75 mm Power +04.0
SN: x00101

MODEL
68UV
DIOPTER
+04.0

I-x mm-I LENGTH
13.75mm
OPTIC
6.00mm

OPHTHALMICS

EXP. DATE
2003-04
SN
x00101

SN
x00101

REF # 69040 LOT 0TEST

"A" Factor : P.C. 118.5
Optic Design : Biconvex
Haptic Design : Short C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 69040

[01] 10757770133212 [21] x00101

50168 Rev A

SN: x00101

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye
68UV Posterior Chamber IOL
Length: 13.75 mm Diopter: +04.0
SN: x00101
Optic size: 6.00mm Haptic angulation: Step-vaulted
Optic design: Biconvex
Haptic design: Short C
Placement: Ciliary sulcus or capsular bag
Material: PMMA with UV absorber

Physician: _____

127UV **storz** +04.0
Posterior Chamber IOL
SN: x00201 Length:13.75
Optic Size: 7.00mm Haptic angulation: 10 degrees
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Ciliary sulcus or capsular bag
Material:
PMMA optic with UV absorber, polypropylene haptics with blue dye

storz Model 127UV
Length 13.75 mm Power +04.0
SN: x00201

MODEL
127UV
DIOPTER
+04.0

I-x mm-I LENGTH
13.75mm
OPTIC
7.00mm

OPHTHALMICS

EXP. DATE
2003-04
SN
x00201

SN
x00201

REF # 48040 LOT 0TEST

"A" Factor : P.C. 118.0
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA optic with UV absorber, polypropylene haptics with blue dye
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 48040

[01] 10757770111104 [21] x00201

50159 Rev A

SN: x00201

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye
127UV Posterior Chamber IOL
Length: 13.75 mm Diopter: +04.0
SN: x00201
Optic size: 7.00mm Haptic angulation: 10 degrees
Optic design: Equiconvex
Haptic design: Modified C
Placement: Ciliary sulcus or capsular bag
Material: PMMA optic with UV absorber, polypropylene haptics with blue dye

Physician: _____

95UV **storz** +04.0

Posterior Chamber IOL

SN: x00301 Length:13.75

Optic Size: 7.00mm Haptic angulation: 10 degrees
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Ciliary sulcus or capsular bag
Material:
PMMA with UV absorber

storz Model 95UV
Length 13.75 mm Power +04.0
SN: x00301

MODEL
95UV
DIOPTER
+04.0

I-x mm-I LENGTH
13.75mm
OPTIC
7.00mm

OPHTHALMICS

EXP. DATE
2003-04
SN
x00301

SN
x00301

REF # 59040 LOT 0TEST

"A" Factor : **P.C. 118.0**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 59040

[01] 10757770121592 [21] x00301

50177 Rev A

SN: x00301

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye

95UV Posterior Chamber IOL
Length: 13.75 mm Diopter: +04.0
SN: x00301

Optic size: 7.00mm Haptic angulation: 10 degrees
Optic design: Equiconvex
Haptic design: Modified C
Placement: Ciliary sulcus or capsular bag
Material: PMMA with UV absorber

Physician: _____

P010UV **storz** +04.0

Posterior Chamber IOL

SN: x00401 Length:13.75

Optic Size: 6.50mm Haptic angulation: 10 degrees
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Ciliary sulcus or capsular bag
Material:
PMMA with UV absorber

storz Model P010UV
Length 13.75 mm Power +04.0
SN: x00401

MODEL
P010UV
DIOPTER
+04.0

I-x mm-I LENGTH
13.75mm
OPTIC
6.50mm

OPHTHALMICS

EXP. DATE
2003-04
SN
x00401

SN
x00401

REF # 1C040 LOT 0TEST

"A" Factor : **P.C. 118.0**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 1C040

[01] 10757770083883 [21] x00401

50050 Rev A

SN: x00401

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye

P010UV Posterior Chamber IOL
Length: 13.75 mm Diopter: +04.0
SN: x00401

Optic size: 6.50mm Haptic angulation: 10 degrees
Optic design: Equiconvex
Haptic design: Modified C
Placement: Ciliary sulcus or capsular bag
Material: PMMA with UV absorber

Physician: _____

P359UV **storz** +04.0

Posterior Chamber IOL

Control:x00101 Length:12.25

Optic Size:5.50mm
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Capsular bag
Material:
PMMA with UV absorber
Haptic angulation: Step-vaulted

storz Model P359UV
Length 12.25 mm Power +04.0
Control # x00101

MODEL
P359UV
+04.0
DIOPTER

LENGTH
12.25mm
5.50mm
OPTIC

OPHTHALMICS

EXP. DATE
2000-01
x00101
CONTROL #

Control # x00101

Part # **2R040** Batch # **0TEST**

"A" Factor : **P.C. 118.0**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber

Control # x00101

PART # 2R040

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye

P359UV Posterior Chamber IOL
Length: 12.25 mm **Diopter: +04.0**
Control # x00101

Optic size: 5.50mm
Optic design: Equiconvex
Haptic design: Modified C
Placement: Capsular bag
Material: PMMA with UV absorber
Haptic angulation: Step-vaulted

Physician: _____

P329UV **storz** +04.0

Posterior Chamber IOL

Control:x00201 Length:12.00

Optic Size:5.00 x 6.00mm
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Capsular bag
Material:
PMMA with UV absorber
Haptic angulation: Step-vaulted

storz Model P329UV
Length 12.00 mm Power +04.0
Control # x00201

MODEL
P329UV
DIOPTER
+04.0

LENGTH
12.00mm
OPTIC
5.00 x 6.00mm

OPHTHALMICS

EXP. DATE
2003-04
SN
x00601

SN
x00601

REF # **2C040** LOT **0TEST**

"A" Factor : **P.C. 118.4**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber

Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 2C040

[01] 10757770090300 [21] x00601

SN: x00601

50063 Rev A

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye

P329UV Posterior Chamber IOL
Length: 12.00 mm **Diopter: +04.0**
SN: x00601

Optic size: 5.00 x 6.00mm
Optic design: Equiconvex
Haptic design: Modified C
Placement: Capsular bag
Material: PMMA with UV absorber
Haptic angulation: Step-vaulted

Physician: _____

S122UV **storz** +04.0
Anterior Chamber IOL
SN: x00101 Length:12.50
Optic Size:6.00mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified S
Placement: Anterior Chamber
Material:
PMMA with UV absorber

storz Model S122UV
Length 12.50 mm Power +04.0
SN: x00101

MODEL
S122UV
DIOPTER
+04.0

|-x mm-| LENGTH
12.50mm
OPTIC
6.00mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x00101

SN
x00101

REF # 8T040 LOT 0TEST

"A" Factor : A.C. 115.8
Optic Design : Equiconvex
Haptic Design : Modified S
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 8T040

[01] 10757770150639 [21] x00101

50142 Rev A

SN: x00101

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye
S122UV Anterior Chamber IOL
Length: 12.50 mm Diopter: +04.0
SN: x00101
Optic size: 6.00mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified S
Placement: Anterior Chamber
Material: PMMA with UV absorber

Physician: _____

BV359 **storz** +04.0
Posterior Chamber IOL
SN: x00401 Length:12.25
Optic Size:5.50mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Capsular bag
Material:
One piece PMMA with UV absorbing optic and blue haptic

storz Model BV359
Length 12.25 mm Power +04.0
SN: x00401

MODEL
BV359
DIOPTER
+04.0

|-x mm-| LENGTH
12.25mm
OPTIC
5.50mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x00401

SN
x00401

REF # 4U040 LOT 0TEST

"A" Factor : P.C. 118.0
Optic Design : Equiconvex
Haptic Design : Modified C
Material : One piece PMMA with UV absorbing optic and blue haptic
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 4U040

[01] 10757770109170 [21] x00401

50009 Rev A

SN: x00401

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye
BV359 Posterior Chamber IOL
Length: 12.25 mm Diopter: +04.0
SN: x00401
Optic size: 5.50mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Capsular bag
Material: One piece PMMA with UV absorbing optic and blue haptic

Physician: _____

BVR-150S **storz** +04.0
Posterior Chamber IOL
SN: x00701 Length:12.25
Optic Size:5.00mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Capsular bag
Material:
One piece PMMA with UV absorbing optic and blue haptics

storz Model BVR-150S
Length 12.25 mm Power +04.0
SN: x00501

MODEL
BVR-150S
DIOPTER
+04.0

I-x mm-I LENGTH
12.25mm
OPTIC
5.00mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x00701

SN
x00701

REF # LOT
KY040 0TEST

"A" Factor : **P.C. 118.1**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : One piece PMMA with UV absorbing optic and blue haptics
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # KY040

[01] 10757770068699 [21] x00701

50002 Rev A

SN: x00701

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye

BVR-150S Posterior Chamber IOL
Length: 12.25 mm Diopter: +04.0
SN: x00701
Optic size: 5.00mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Capsular bag
Material: One piece PMMA with UV absorbing optic and blue haptics

Physician: _____

BVR-155S **storz** +04.0
Posterior Chamber IOL
SN: x01001 Length:12.25
Optic Size:5.50mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Capsular bag
Material:
One piece PMMA with UV absorbing optic and blue haptics

storz Model BVR-155S
Length 12.25 mm Power +04.0
SN: x01001

MODEL
BVR-155S
DIOPTER
+04.0

I-x mm-I LENGTH
12.25mm
OPTIC
5.50mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x01001

SN
x01001

REF # LOT
K1040 0TEST

"A" Factor : **P.C. 118.1**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : One piece PMMA with UV absorbing optic and blue haptics
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # K1040

[01] 10757770069306 [21] x01001

50004 Rev A

SN: x01001

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye

BVR-155S Posterior Chamber IOL
Length: 12.25 mm Diopter: +04.0
SN: x01001
Optic size: 5.50mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Capsular bag
Material: One piece PMMA with UV absorbing optic and blue haptics

Physician: _____

BVR-160M **storz** +04.0

Posterior Chamber IOL

SN: x00501 Length:12.75

Optic Size: 6.00mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Capsular bag
Material:
One piece PMMA with UV absorbing optic and blue haptics

storz Model BVR-160M
Length 12.75 mm Power +04.0
SN: x00501

MODEL
BVR-160M
DIOPTER
+04.0

LENGTH
12.75mm
OPTIC
6.00mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x00501

SN
x00501

REF # K5040 LOT 0TEST

"A" Factor : **P.C. 118.1**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : One piece PMMA with UV absorbing optic and blue haptics

Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # K5040

[01] 10757770071743 [21] x00501

50005 Rev A

SN: x00501

This certifies that _____ received the following intraocular lens implant in the [ ] Right eye [ ] Left eye

BVR-160M Posterior Chamber IOL
Length: 12.75 mm Diopter: +04.0
SN: x00501

Optic size: 6.00mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Capsular bag
Material: One piece PMMA with UV absorbing optic and blue haptics

Physician: _____

BVR-165L **storz** +04.0

Posterior Chamber IOL

SN: x00201 Length:13.25

Optic Size: 6.50mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Ciliary sulcus or capsular bag
Material:
One piece PMMA with UV absorbing optic and blue haptics

storz Model BVR-165L
Length 13.25 mm Power +04.0
SN: x00201

MODEL
BVR-165L
DIOPTER
+04.0

LENGTH
13.25mm
OPTIC
6.50mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x00201

SN
x00201

REF # YA040 LOT 0TEST

"A" Factor : **P.C. 118.1**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : One piece PMMA with UV absorbing optic and blue haptics

Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # YA040

[01] 10757770080868 [21] x00201

50007 Rev A

SN: x00201

This certifies that _____ received the following intraocular lens implant in the [ ] Right eye [ ] Left eye

BVR-165L Posterior Chamber IOL
Length: 13.25 mm Diopter: +04.0
SN: x00201

Optic size: 6.50mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Ciliary sulcus or capsular bag
Material: One piece PMMA with UV absorbing optic and blue haptics

Physician: _____

EZE-50 **storz** **+04.0**
Posterior Chamber IOL
SN: x00801 Length:12.75

Optic Size:5.00mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Capsular bag
Material:
PMMA with UV absorber

storz Model EZE-50
Length 12.75 mm Power +04.0
SN: x00901

MODEL
EZE-50
DIOPTER
+04.0

I-x mm-I LENGTH
12.75mm
OPTIC
5.00mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x00901

SN
x00901

REF # LOT
8M040 0TEST

"A" Factor : **P.C. 118.1**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 8M040

[01] 10757770148346 [21] x00901

50025 Rev A

SN: x00901

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye
EZE-50 Posterior Chamber IOL
Length: 12.75 mm Diopter: +04.0
SN: x00901
Optic size: 5.00mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Capsular bag
Material: PMMA with UV absorber

Physician: _____

EZE-55 **storz** **+04.0**
Posterior Chamber IOL
SN: x01101 Length:12.75

Optic Size:5.50mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Capsular bag
Material:
PMMA with UV absorber

storz Model EZE-55
Length 12.75 mm Power +04.0
SN: x01101

MODEL
EZE-55
DIOPTER
+04.0

I-x mm-I LENGTH
12.75mm
OPTIC
5.50mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x01101

SN
x01101

REF # LOT
7W040 0TEST

"A" Factor : **P.C. 118.1**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 7W040

[01] 10757770140227 [21] x01101

50027 Rev A

SN: x01101

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye
EZE-55 Posterior Chamber IOL
Length: 12.75 mm Diopter: +04.0
SN: x01101
Optic size: 5.50mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Capsular bag
Material: PMMA with UV absorber

Physician: _____

EZE-65 **storz** +04.0
Posterior Chamber IOL
SN: x00301 Length:13.25
Optic Size:6.50mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Ciliary sulcus or capsular bag
Material:
PMMA with UV absorber

storz Model EZE-65
Length 13.25 mm Power +04.0
SN: x00301

MODEL
EZE-65
DIOPTER
+04.0

I-x mm-I LENGTH
13.25mm
OPTIC
6.50mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x00301

SN
x00301

REF # LOT
8N040 0TEST

"A" Factor : **P.C. 118.1**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 8N040

[01] 10757770148957 [21] x00301

50033 Rev A

SN: x00301

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye
EZE-65 Posterior Chamber IOL
Length: 13.25 mm Diopter: +04.0
SN: x00301
Optic size: 6.50mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Ciliary sulcus or capsular bag
Material: PMMA with UV absorber

Physician: _____

P484UV **storz** +04.0
Posterior Chamber IOL
SN: x00601 Length:13.00
Optic Size:6.50mm Haptic angulation: 10 degress
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Ciliary sulcus or capsular bag
Material:
PMMA with UV absorber

storz Model P484UV
Length 13.00 mm Power +04.0
SN: x01101

MODEL
P484UV
DIOPTER
+04.0

I-x mm-I LENGTH
13.00mm
OPTIC
6.50mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x01101

SN
x01101

REF # LOT
5Q040 0TEST

"A" Factor : **P.C. 117.9**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 5Q040

[01] 10757770117939 [21] x01101

50090 Rev A

SN: x01101

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye
P484UV Posterior Chamber IOL
Length: 13.00 mm Diopter: +04.0
SN: x01101
Optic size: 6.50mm Haptic angulation: 10 degress
Optic design: Equiconvex
Haptic design: Modified C
Placement: Ciliary sulcus or capsular bag
Material: PMMA with UV absorber

Physician: _____

P517UV **storz** +04.0
Posterior Chamber IOL
SN: x00901 Length:13.25

Optic Size:6.50mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Ciliary sulcus or capsular bag
Material:
PMMA with UV absorber

storz Model P517UV
Length 13.25 mm Power +04.0
SN: x01201

MODEL
P517UV
DIOPTER
+04.0

|-x mm-| LENGTH
13.25mm
OPTIC
6.50mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x00901

SN
x00901

REF # **6L040** LOT **0TEST**

"A" Factor : **P.C. 118.0**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 6L040

[01] 10757770127709 [21] x00901

50109 Rev A

SN: x00901

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye

P517UV Posterior Chamber IOL
Length: 13.25 mm Diopter: +04.0
SN: x00901

Optic size: 6.50mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Ciliary sulcus or capsular bag
Material: PMMA with UV absorber

Physician

P574UV **storz** +04.0
Posterior Chamber IOL
SN: x01201 Length:13.25

Optic Size:6.00mm Haptic angulation: Step-vaulted
Optic Design: Equiconvex
Haptic Design:
Modified C
Placement: Ciliary sulcus or capsular bag
Material:
PMMA with UV absorber

storz Model P574UV
Length 13.25 mm Power +04.0
SN: x01201

MODEL
P574UV
DIOPTER
+04.0

|-x mm-| LENGTH
13.25mm
OPTIC
6.00mm

OPHTHALMICS

EXP. DATE
2003-02
SN
x01201

SN
x01201

REF # **8J040** LOT **0TEST**

"A" Factor : **P.C. 118.1**
Optic Design : Equiconvex
Haptic Design : Modified C
Material : PMMA with UV absorber
Caution: Federal [USA] Law restricts this device to sale by or on the order of a physician.

REF # 8J040

[01] 10757770147554 [21] x01201

50125 Rev A

SN: x01201

This certifies that _____
received the following intraocular lens implant in the
[ ] Right eye [ ] Left eye

P574UV Posterior Chamber IOL
Length: 13.25 mm Diopter: +04.0
SN: x01201

Optic size: 6.00mm Haptic angulation: Step-vaulted
Optic design: Equiconvex
Haptic design: Modified C
Placement: Ciliary sulcus or capsular bag
Material: PMMA with UV absorber

Physician