DEVICE DESCRIPTION

The aspicio™ Toric Soft Hydrophobic Intraocular Lenses (TR60C, TR60Y) are foldable one-piece posterior chamber, Clear (UV absorbing) or Yellow (UV+blue light absorbing) optical implant lenses used for the replacement of the human crystalline lens in the visual correction of aphakia and pre-existing corneal astigmatism in adult patients, with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder, and increased spectacle independence for distance vision. The yellow aspicio™ Toric IOL contains ICARES Medicus' proprietary blue light filtering chromophore that filters light in a manner that approximates a young human crystalline lens in the 400-475 nm blue light wavelength range.

The aspicio™ Toric Soft Hydrophobic Intraocular Lens (TR60C, TR60Y) is a foldable posterior chamber, one-piece acrylic lens with square edge, a 6.0 mm optic, and an overall length of 13.0 mm. All models are manufactured at the following diopter power range: +4.0 D to +34.0 D in 0.5 diopter increments with an added cylindrical power of 1.0 to 6.0 D in 0.5 D increments as indicated by the axis orientation marks on the anterior optic surface to achieve visual correction of aphakia and pre-existing corneal astigmatism. Refractive index of the lens is 1.5.

The astigmatism to be corrected by the aspicio™ Toric IOL model TR60Y and TR60C shall be determined by keratometry and biometry data keeping in mind that the size and location of the surgical incision can affect the amount and axis of corneal astigmatism. To optimize the selection of the proper aspicio™ Toric IOL lens power, a web-based calculator (www.icaresmedicus.com) is provided for the surgeon. When the pre-operative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are entered, the web-based calculator will determine the appropriate TR60Y or TR60C Toric IOL lens spherical dioptric power, cylinder power, and axis of placement in the eye to be implanted.

MODE OF ACTION

The aspicio™ Toric posterior chamber intraocular lenses are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. The aspicio™ Toric IOLs have a toric aspheric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). Alignment of the toric IOL cylinder axis marks with the post-operative steep corneal meridian allows the lens to correct astigmatism. The toric aspheric optic reduces spherical aberration as compared to a standard spherical toric optic in an average eye.

INDICATIONS

The aspicio™ Toric IOLs are indicated for primary implantation for the visual correction of pre-existing corneal astigmatism and aphakia in adult patients, with and without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder, and increased spectacle independence for distance vision following removal of a cataractous lens. The device is intended to be placed in the capsular bag by an ophthalmologist following successful circular tear anterior capsulotomy with a verified absence of radial tears.

WARNINGS

Physicians considering lens implantation should weigh the potential risk/benefit ratio for any circumstances that could increase complications or impact patient outcomes. This lens should not be implanted under the following conditions:

1. *If the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned.*
2. *The Tyvek pouch is found to be damaged or opened.*
3. *Suspected microbial infection.*
4. *Recurrent severe anterior or posterior segment inflammation or uveitis.*
5. *Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment disease.*
6. *Surgical difficulties at the time of cataract extraction that might increase the potential for complications (e.g. persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).*
7. *A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.*
8. *Circumstances that would result in damage to the endothelium during implantation.*
9. *Children under the age of 2 years are not suitable for intraocular lenses.*

PRECAUTIONS

1. *Do not resterilize the lens by any method.*
2. *Do not store the lens at a temperature lower than 5°C or greater than 25°C.*
3. *Do not reuse the lens. The lens is for single use only.*
4. *Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to rinse/or soak lenses.*
5. *Accurate keratometry and biometry in addition to the use of the Toric Calculator (www.icaresmedicus.com) are recommended to achieve optimal visual outcome.*
6. *Handle lenses carefully to avoid damage to lens surface or haptics.*
7. *Do not attempt to reshape haptics in any way.*
8. *A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lens.*
9. *Rotation of aspicio™ Toric IOLs away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, the lens repositioning should occur as early as possible prior to lens encapsulation. Some clinical cases suggest encapsulation is complete within four weeks of implantation.*
10. *Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may allow the lens to rotate causing misalignment of the aspicio™ Toric IOL with the intended axis of placement.*

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 diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ration before implanting a lens in a patient with one or more of the following conditions.

Before Surgery:

1. Choroidal hemorrhage
2. Concomitant severe eye disease
3. Extremely shallow anterior chamber
4. Microphthalmos
5. Non-age-related cataract
6. Proliferative diabetic retinophathy (severe)
7. Severe corneal dystrophy
8. Severe optic nerve atrophy
9. Irregular corneal astigmatism
10. Medically uncontrolled glaucoma
11. Chronic severe uveitis
12. Diabetic retinopathy
13. Clinically significant macular/RPE changes

During Surgery:

1. Excessive vitreous loss
2. Capsulotomy by any technique other than a circular tear
3. The presence of radial tears known or suspected at the time of surgery
4. Situation in which the integrity of the circular tear cannot be confirmed by direct visualization
5. Cataract extraction by techniques other than phacoemulsification or liquefaction
6. Situation where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
7. Posterior capsular rupture (preventing fixation of IOL)
8. Zonular damage (Preventing fixation of IOL)
9. Uncontrollable positive pressure
10. Significant anterior chamber hyphema

COMPLICATIONS

The following lists potential complications accompanying cataract or implant surgery. Complications may include, but are not limited to the following:

Post-Operative Adverse Events:

1. Lens rotation
2. Visual distortion
3. Blurred vision at near distance

Cumulative Adverse Events:

1. Corneal endothelial damage
2. Infection (endophthalmitis)
3. Hyphema
4. Hypopyon
5. Lens Dislocation
6. Cystoid macular edema
7. Corneal edema
8. Pupillary block
9. Cyclitic membrane
10. Iris prolapse
11. Retinal detachment
12. Vitritis
13. Transient or persistent glaucoma
14. Secondary surgical intervention (excluding retinal detach ment and posterior capsulotomy), include, but not limited to the following:
    a. Iridectomy for pupillary block
    b. Vitreous aspiration for pupillary block
    c. Repositioning of lens
    d. IOL removal for inflammation
    e. IOL replacement
    f. Wound leak repair

Persistent Adverse Events:

1. Corneal Stroma Edema
2. Cystoid Macular Edema
3. Iritis
4. Raised IOP requiring treatment

SELECTION AND PLACEMENT OF THE aspicio™ TORIC IOL

The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. In order to optimize IOL selection and axis placement, ICARES provides a web-based tool (www.icaresmedicus.com) for the surgeon. Pre-operative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate aspicio™ Toric IOL model, spherical equivalent lens power, and axis of placement in the eye.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The anterior surface of the IOL is marked with indentations (three at each end) at the haptic/optic junction that identify the flat meridian of the aspicio™ Toric IOL optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90° away). The aspicio™ Toric IOL cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement).

Prior to surgery the operative eye should be marked in the following manner:

With the patient sitting upright, precisely mark the twelve o'clock and/or the six o'clock position with a T marker, a surgical skin marker, or a marking pencil indicated for ophthalmic use. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement following the use of the web-based www.icaresmedicus.com to determine the optimal axis of placement.

After the lens is inserted, precisely align the axis marking indentations on the aspicio™ Toric IOL with the marked axis of lens placement. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. This may be accomplished by manipulating the IOL optic with the I/A tip and using standard irrigation/aspiration techniques to remove all viscoelastic from the eye. Bimanual techniques may be used, if preferred, to ensure removal of viscoelastic from behind the lens implant. Special care should be taken to ensure proper positioning of the aspicio™ Toric IOL at the intended axis following viscoelastic removal. Residual viscoelastic may allow the lens to rotate causing misalignment of the aspicio™ Toric IOL with the intended axis of placement.

Misalignment of the axis of the lens with the intended axis of placement may compromise its astigmatic correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the aspicio™ Toric IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the aspicio™ Toric IOL after implantation. In order to minimize this effect, the surgeon should be careful to ensure that preoperative keratometry and biometry is accurate and that the IOL is properly oriented prior to the end of surgery.

DIRECTIONS FOR USE

1. Examine the label on the lens box for proper lens model, diopter power and expiration date.
2. Open the lens box to remove the pouched lens and verify the lens case information (e.g. power, model and serial numbers) is consistent with the information on the outer box.
3. This device is sterile until the inner pouch is opened. Inspect the pouch carefully for tears, cuts, punctures or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised.
4. To remove the lens, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. To minimize the occurrence of marks on the lens due to handling, all instrumentation should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.
6. When removing the lens from the case, DO NOT grasp the optic area with forceps. The lens should be handled by the haptic portion only. Handle the lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.
7. Rinse the lens thoroughly using sterile intraocular irrigating solution such as BSS® or BSS PLUS® solution. DO NOT rinse the IOL in solutions other than sterile intraocular irrigating solution. Prior to insertion, the IOL should be carefully examined to ensure that particles have not adhered during handling.
8. ICARES Medicus, Inc. recommends using the lioli™ IOL Delivery System, pioli™ IOL Delivery System, or other equivalent commercial available delivery system. For lioli™ IOL Delivery System, LIOLI-18 only validated up to +20D hydrophobic intraocular lenses. LIOLI-22 and LIOLI-24 are validated up to +30D hydrophobic intraocular lenses. For pioli™ IOL Delivery System, PIOLI-D is validated up to +28D hydrophobic intraocular lenses. Failure to follow the instructions for use may result in patient injury. Sodium hyaluronate-based viscoelastic solution is recommended to be used with lioli™ and pioli™ IOL delivery systems. For the methods of loading the lens onto the injector, please refer to respective IFU of the IOL delivery system used during the surgical procedure.
9. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery.
10. DO NOT reuse this IOL. The device is for single use only. Reuse could result in device contamination or damage to IOL or cartridge.
11. DO NOT RESTERILIZE.

PATIENT REGISTRATION AND REPORTING

Contact local distributors regarding any reports of adverse events.

HOW SUPPLIED

The aspicio™ Toric Soft Hydrophobic Intraocular Lens (TR60C, TR60Y) is supplied dry, in a lens tray packaged in a Tyvek peel pouch and terminally sterilized by ethylene oxide. The Lens must be opened only under aseptic conditions (See DIRECTIONS FOR USE above).

EXPIRATION DATE

The packaged aspicio™ Toric Soft Hydrophobic Acrylic Intraocular Lens is sterile unless the Tyvek peel pouch is damaged or opened. The sterility expiration date is clearly indicated on the outside of lens package. DO NOT IMPLANT the aspicio™ Toric IOL after the expiration date. Any lens held after the expiration date should be returned to the distributor.

TRANSMITTANCE COMPARISON

Model	Characteristics	UV Cutoff at 10% T
Yellow (TR60 Y)	UV-Absorber + blue light filter	≥ 384 nm
Non–Yellow (TR60 C)	UV-Absorber	≥ 382 nm

CHINESE

產品敘述

愛視睫散光矯正型人工水晶體（型號：TR60Y、TR60C，以下簡稱本產品），為一可折疊式單片後房型，用於取代人類水晶體之光學植入性醫療器材。本產品鏡面上標有柱狀軸記號，以矯正無水晶體症及已存在之角膜散光問題；同時透過屈光度設計，改善患者矯正前之遠、近距視力，減低殘餘柱狀屈光並減少患者對視遠眼鏡的依賴性。

本產品類型分為透明片及黃片，透明片及黃片皆可取代人眼天然水晶體，並過濾紫外線。其中黃片具有藍光過濾色基（chromophore），使其過濾400至475nm波長光線的能力近似於年輕人類水晶體（Boettner and Wolter, 1962）；故除了擁有透明片可過濾紫外線之功能外，黃片還可降低藍光穿透率—可過濾約20%波長為400nm的藍光，而波長475nm的藍光可過濾約8%（參見表一: 屈光度20.0D之人工水晶體光穿透度比較表）。

使用TR60C或TR60Y型號愛視睫散光矯正型人工水晶體進行散光矯正時，必須根據角膜弧度量測與生物量測之資料進行評估，且須注意手術切口大小及位置亦會對角膜散光之程度及軸性位置造成影響。為了協助醫師選出最適合的愛視睫散光矯正型人工水晶體，可參考本公司所提供的網站計算工具(www.icaresmedicus.com)，只要輸入角膜弧度量測值、生物量測值、切口位置以及估計因手術引起的角膜散光數值等，此網路計算工具便可算出合適的愛視睫散光矯正型人工水晶體之球面等同屈光度、柱狀度數、以及植入眼內的軸性位置。

產品規格

型號	TR60C	TR60Y
顏色	透明	黃色
材料	可吸收紫外線之疏水性丙烯酸酯	可吸收紫外線、藍光之疏水性丙烯酸酯
UV cutoff at 10% T	≥ 382 nm	≥ 384 nm
設計	單片疏水性折疊式後房型散光矯正非球面人工水晶體	
視盤直徑	6.0mm	
全長	13.0mm	
光學設計	直角切割	
球面等同屈光度範圍	4.0 D至34.0 D，以0.5 D遞增	
柱狀度數範圍	1.0 D至6.0 D，以0.5 D遞增	
折射率	1.5	
材料水分含量	<0.5%	
常數A值	118.4	
滅菌方式	環氧乙烷（EtO）	
包裝	人工水晶體乾式保存於一水晶體托盤中，並置於一Tyvek®封口袋	

作用原理

本產品適用植入至眼睛後房，用以取代天然水晶體的功用，且作為折射介質來矯正無水晶體症狀。本產品為非球面設計並有散光矯正功能，鏡面上亦有柱狀軸記號來標示較平的經線（加上正柱狀軸）。調整柱狀軸記號使其與術後角膜曲度較大的經線對齊即可達到矯正散光之效果。相較於一般標準球面散光矯正鏡面，本非球面散光矯正鏡面可降低球面像差。

適應症

本產品適用於取代人類水晶體以矯正無晶體及術前有角膜散光成人患者的視力，不論患者是否具有老花眼、近視眼症狀，也能在白內障手術後改善患者未矯正之遠近距視力、減低殘餘柱狀屈光並減少患者對視遠眼鏡的依賴性。本產品使用時必須經由專業眼科醫生在已確認無徑向撕裂的成功水晶體後囊袋環狀切開術後植入至水晶體後囊袋中。

警告

考慮進行人工水晶體植入手術的醫生，都應對於手術可能引起的併發症或是影響患者治療效果的任何情況權衡潛在的風險/療效比。發生下列狀況時，都不應植入人工水晶體：

1. 水晶體後囊袋破損、韌小帶受損或是已預計會施行後囊撕開術
2. 塑膠盒Tyvek®包裝紙損壞
3. 疑似微生物感染
4. 反覆發生嚴重的眼前段或眼後段炎症及葡萄膜炎患者。
5. 植入人工水晶體後可能會影響眼後段疾病的觀察、診斷、治療能力的患者
6. 白內障摘除手術不順，可能增加出現併發症的風險。如持續性出血、虹膜嚴重受損、不可控制的眼壓升高或者嚴重的玻璃體脫出、流失
7. 因過往之外傷或先天性缺陷導致眼部變形，無法適當支撐人工水晶體
8. 植入過程中會導致內皮細胞損傷
9. 未滿2歲的兒童不適合植入人工水晶體

注意事項

1. 請勿以任何方法將人工水晶體重複滅菌。
2. 請勿將人工水晶體儲存於溫度高於25℃以上，低於5℃以下的環境。
3. 請勿重複使用人工水晶體，本產品僅限單次使用。
4. 請使用無菌的眼內灌注液（如均衡鹽溶液BSS®或是BSS PLUS®）來潤濕或浸泡人工水晶體。
5. 為達理想的術後視力表現，建議需有精確的角膜弧度量測以及生物量測，並參考使用本公司提供的網站計算工具(www.icaresmedicus.com)。
6. 請小心操作人工水晶體以避免造成人工水晶體表面或支撐腳的損傷。
7. 請勿以任何方式改變支撐腳的形狀。
8. 需要高度的手術技術來植入人工水晶體，施行手術的醫師在植入此人工水晶體前應曾有觀察或是協助植入的經驗，並且成功地完成一至數個相關的人工水晶體植入課程。
9. 本產品旋轉超過原先預計放置的軸性位置時，會減低矯正散光的效果。當偏離超過30°時會導致術後柱狀屈光現象增加，如果需要，要在人工水晶體與囊袋黏合前將人工水晶體調整至適當位置。一些臨床研究顯示，約要在植入後4週內會形成人工水晶體與囊袋完全黏合的現象。
10. 需小心地移除不論是在人工水晶體前方或後方的眼科黏彈劑，殘餘的眼科黏彈劑可能會造成愛視睫散光矯正型人工水晶體旋轉而偏離原先預計放置的軸性位置。

禁忌

存在下列任一情況的患者可能不適合植入人工水晶體，因為人工水晶體可能使已存在的情況加重，可能干擾某一疾病的診斷或治療，或者可能有危害患者視力的風險。病人如有以下一項或是多項狀況時，醫師應仔細地做術前評估和合理的臨床判斷來評估其手術的優點/風險比例。

病人手術前狀況：

1. 脈絡膜出血
2. 伴隨嚴重的眼睛疾病
3. 前房過窄
4. 小眼畸形
5. 非年紀因素的白內障
6. 增殖性糖尿病視網膜病變（嚴重）
7. 嚴重角膜失養症
8. 嚴重的視神經萎縮
9. 非規則性角膜散光
10. 無法控制的青光眼
11. 慢性葡萄膜炎
12. 糖尿病視網膜病變
13. 臨床顯著黃斑/視網膜色素上皮（RPE）變性

病人手術中狀況：

1. 玻璃體嚴重流失
2. 除了環狀撕開術外的任何囊袋撕除術
3. 術中出現已知或可能的的放射線狀的撕裂
4. 無法以目視的方式來判定環狀撕開傷口是否完整時
5. 白內障的摘除並非經由超音波晶體乳化術或是液化作用時
6. 當已預期會需要較大的囊撕開術時（如：糖尿病、另一眼已有視網膜剝離、周邊視網膜病變等）
7. 水晶體後囊袋破裂（妨礙人工水晶體固定）
8. 韌小帶受損（妨礙人工水晶體固定）
9. 無法控制的眼壓升高
10. 嚴重的前房出血

副作用與併發症：

白內障手術與人工水晶體植入術可能引發的併發症如下(但不限於下列反應)：

累積的不良反應事件：

1. 角膜內皮細胞受損
2. 感染（眼內炎）
3. 前房積血
4. 前房積膿
5. 水晶體脫位
6. 黃斑部囊狀水腫
7. 角膜水腫
8. 瞳孔閉鎖
9. 睫狀體炎
10. 虹膜脫出
11. 視網膜剝離
12. 玻璃體炎
13. 眼內感染
14. 暫時性或持續性青光眼
15. 二次手術干預（不包括視網膜剝離和後囊膜切開術），包括但不限於以下：
    a)因瞳孔閉鎖而施行的虹膜切除術
    b)因瞳孔閉鎖而施行的玻璃體吸除術
    c)人工水晶體復位
    d)因發炎移除人工水晶體
    e)人工水晶體重新置換
    f)切口隙漏修復

持續的不良反應事件：

1. 角膜基質水腫
2. 黃斑部囊狀水腫
3. 虹膜炎
4. 眼壓升高需要治療

本產品的選擇與放置

為了矯正散光，應注重角膜弧度量測與生物量測勝於屈光數值，因為水晶體上存有晶體散光會因被移除而影響結果。手術切口的大小及位置與角膜的軸性散光會有很大的影響。為了達到最理想的人工水晶體選擇與軸性位置，本公司提供一個網路工具(www.icaresmedicus.com)給醫師參考。考量術前的角膜弧度量測、生物量測、切口位置及預期手術所引起的角膜散光後，選出建議的型號，球面等同屈光度以及放置於眼內的軸性位置。

為了達到最佳結果，醫師必須確定正確的放置並旋轉人工水晶體於水晶體囊袋中。在人工水晶體的前側表面的視盤與支撐腳相接處上有個獨特記號(三個凹點)用於指出本產品視盤的較平坦的經線位置。這些獨特的記號就代表一個想像的增加柱狀軸位置 (註：人工水晶體較陡的柱狀經線相距90°)。本產品的柱狀軸標示應與切口後較陡的角膜經線成一直線(放置於預先設想的軸性位置)。

術前應利用下列方式對將進行手術的眼睛做記號：
病患應為坐直，12點鐘和6點鐘方向應利用適合眼科使用的手術記號器或是記號筆精確地做一個“T”型記號。使用這些記號作為一個參考點，在手術前與手術中即產生一個參考放置人工水晶體的軸性位置，並使用www.icaresmedicus.com網站來確認應放置的精確軸性位置。

一旦人工水晶體被植入後，人工水晶體上的軸性記號應與所做的應放置軸性記號精確地對準。小心地移除人工水晶體前後表面的眼科黏彈劑。可利用I/A探針與標準的灌注/吸除技巧來完全地移除眼內的眼科黏彈劑。如果喜歡，也可以使用雙手分別操作Irrigation與Aspiration兩器械，來確保已移除所植入之人工水晶體後方的眼科黏彈劑。應特別小心地確認在眼科黏彈劑移除後，本產品仍被放置於預計的軸性位置處。殘留的眼科黏彈劑可能會導致人工水晶體旋轉而使愛視睫散光矯正型人工水晶體偏離原先預定放置的軸性位置。

若偏離了人工水晶體原先預定放置的軸性位置，可能會影響散光的矯正效果。不正確的校準可能是因為下列因素所造成：不精確的角膜弧度量測與角膜記號、在手術過程中沒有精確的將本產品放置到預期的軸性位置、無法預期的手術過程導致角膜改變、醫師在植入後轉動本產品。為了使這些影響降至最低，必須小心地確定術前的角膜弧度量測與生理量測的準確度，以及手術過程中人工水晶體需保持在適當位置。

使用說明

1. 檢查外盒標籤上的型號、度數及有效期限
2. 打開外盒，取出內裝有人工水晶體的包裝袋，核對水晶體托盤上的產品資訊（如：人工水晶體度數、型號及序號）是否與外盒上提供的資訊一致。
3. 在內層包裝袋為完整未被破壞或開封時可確定本產品為無菌狀態，請小心檢查包裝袋是否有撕裂、缺口、穿孔或是其他被打開或破壞的跡象。若產品已非無菌狀態，切勿使用。
4. 打開完整未受損的包裝袋，並將水晶體托盤移放至無菌區，接著小心將水晶體托盤上蓋旋開便可看見人工水晶體。
5. 為了盡量減少人為操作而造成的人工水晶體損傷，所有操作器械必須完全潔淨、所有使用的鑷子必須為圓頭設計且具平滑表面。
6. 將人工水晶體從托盤取出時，請勿使用鑷子夾取人工水晶體的光學區，僅可夾取支撐腳部位。請小心操作人工水晶體以避免造成人工水晶體表面或支撐腳的損傷。請勿以任何方式改變支撐腳的形狀。
7. 請使用無菌的眼內灌注液，如BSS®或是BSS PLUS®均衡鹽溶液將潤濕人工水晶體完全潤濕。請勿使用任何非無菌的眼內灌注液潤濕人工水晶體。植入前，請仔細檢查人工水晶體以確保操作過程中無異物附著於人工水晶體表面。
8. 應用奈米醫材建議本產品搭配lioli™或pioli™人工水晶體導引器(衛部醫器輸壹字第015055號)，或市面上與其具有等同性的產品使用。
9. 有多種手術步驟可以被使用，醫師應依患者需求選擇最適合的方式。醫師在進行手術前須確認是否有適合的用具能使用。
10. 請勿重複使用人工水晶體，本產品僅限單次使用。重複使用本產品，可能造成潛在的重複或交叉感染，導致病患發生感染或需移除植入物。
11. 請勿重複滅菌。

患者登記與通報

不良事件回報請聯絡當地經銷商。

包裝

本產品均乾燥儲存在水晶體盒（含蓋）中，並置於一Tyvek®封口袋中，最後以環氧乙烷(EtO)滅菌處理，使用時只能在無菌的狀態下打開（參考上述使用說明）。

有效期限

完整包裝的愛視睫散光矯正型人工水晶體在Tyvek®密封層為完整未被破壞或開封時，可確定本產品為無菌狀態。保存期限已清楚地標示在外包裝盒上，若已超過保存期限，切勿使用本產品進行植入手術。任何逾期產品請退還給經銷商。

CE 2460

衛部醫器製字第006230號

aspicil™

Soft Hydrophobic Intraocular Lens

愛視睫散光矯正型人工水晶體 TORIC

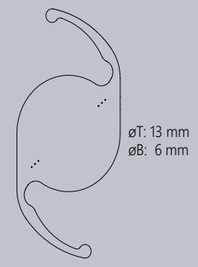
Instructions For Use

使用前請務必詳閱原廠之使用說明書遵照指示使用

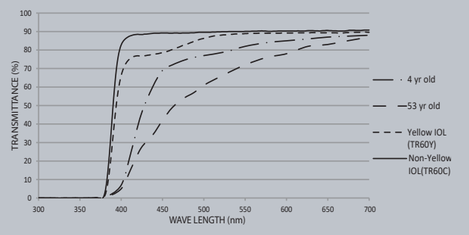
CAUTION: Professional Use Only

Clear　Yellow

物理特性
散光矯正單片型



20D 人工水晶體光譜穿透曲線



備註：

1. 本圖之穿透率數值，使用6mm光圈和等同於屈光度20.0D透鏡光學中心厚度的光盤進行實驗所得到的結果
2. 本產品黃片人工水晶體(TR60Y)之10%透光率UV截止波長為384 nm
3. 人體水晶體數據來自Boettner and Wolter (1962)

表一: 屈光度20.0D之人工水晶體光穿透度比較表

型號	400nm	425nm	450nm	475nm
TR60C(%)	82.8	88.4	89.2	89.2
TR60Y(%)	66.3	76.8	78.6	82.4
穿透差 (%)	16.5	11.6	10.6	6.8
穿透差異百分比 (%)	19.93	13.12	11.88	7.62

備註:

1. 穿透差(%) = TR60C(%)-TR60Y(%)
2. 穿透差異百分比(%)= 穿透差(%)÷TR60C(%)×100(%)

	製造商 Manufacturer	SN	序號 Serial Number
	請勿重複滅菌 Do not resterilize		請勿重複使用 Do not re-use
	保存期限 Use-by date (YYYY-MM-DD)		警告 Caution
	詳閱使用說明 Consult instructions for use		包裝如有損壞則請勿使用 Do not use if package is damaged
STERILE EO	利用環氧乙烷滅菌 Sterilized using ethylene oxide	EC REP	授權歐體代表 Authorized Representative in the European Community
	遠離日曬 Keep away from sunlight		保持乾燥 Keep dry
5℃ 25℃	保存溫度限制 Temperature limit		製造日期 Date of Manufacture (YYYY-MM-DD)
CYL	柱狀度數 Cylinder		

製造廠 / 藥商名稱：應用奈米醫材科技股份有限公司

製造廠 / 藥商地址：新竹縣竹北市新竹科學園區生醫路二段16號4樓

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