

“酷柏” 佰美視雙週拋軟式隱形眼鏡
“CooperVision” Biomedics 55 (Ocufilecon D) Soft Contact Lens

使用前請務必詳閱原廠之使用說明書並遵照指示使用

衛署醫器輸字第 022568 號

重要資訊：

此說明書提供眼科專業人員(眼科醫師/驗光師)或配戴者參考，
眼科專業人員須提供配戴者適當之處方鏡片的指導手冊及資訊手冊。

符號檢索：

下列符號可能出現在標籤或包裝上

符 號	處 方
	警示：本裝置由有執照的業者販售或訂購。
	請參照仿單。
	有效日期。
	批號。
	使用濕熱滅菌。

適應症：“酷柏”佰美視雙週拋軟式隱形眼鏡用來矯正非無晶狀體，眼睛無疾病者之近視、遠視，散光須在 2.00 度或以下。本產品為每日配戴，每 2 週更換鏡片。

產品說明：“酷柏”佰美視雙週拋軟式隱形眼鏡其鏡片的材料ocufilcon D 為氫化甲基丙烯酸酯和甲基丙烯酸聚合物。為拿取方便，在交聯前於單體中加入 Vat Blue 6 染料使鏡片呈淡藍色。此鏡片含有 benzophenone 是可吸收 UV 的單層膜，可以阻擋 UV 的輻射，有助於防護有害紫外線對角膜及眼睛的傷害。

“酷柏”佰美視雙週拋軟式隱形眼鏡為半球面片，規格如下所示：

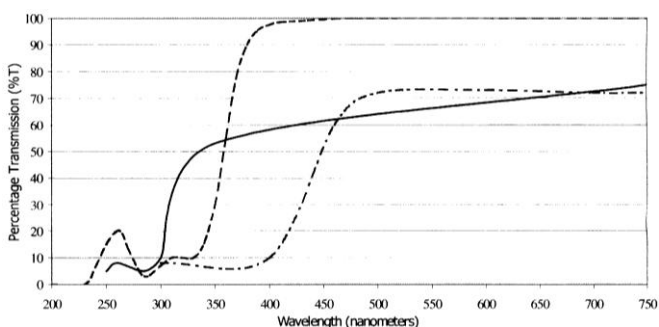
直 徑	12.0 mm ~ 18.00 mm
基 弧	6.50 mm ~ 12.80 mm
中心厚度	0.025 mm ~ 0.40 mm
度數範圍	Plano ~ -10.00D
鏡片顏色	淡藍色
配戴方式	每日配戴，雙週拋

“酷柏”佰美視雙週拋軟式隱形眼鏡的物理係數如下：

折射率	1.41
表面特性	親水性
含水量	55.0%
透氧率	$19.6 \times 10^{-11} (\text{cm}^2/\text{sec}) \text{ ml O}_2$ /ml x mm Hg 於 35°C 時 (Fatt method)
透光率	97.0%

設計：“酷柏”佰美視雙週拋軟式隱形眼鏡是半球面片可以覆蓋角膜且亦可能覆蓋部分鄰近的鞏膜。

-8.00D Ocufilecon D 親水性抗紫外線隱形眼鏡與人類角膜和人類水晶體的透射比變量曲線圖



- - -8.00D Ocufilecon D 抗紫外線隱形眼鏡，中心厚度為 0.06mm
- 人類角膜(24 歲)
- · 人類水晶體(25 歲)

1. Lerman, S., 「輻射能量與眼睛」(紐約：MacMhian, 1980), P. 58, 圖 2-21 一個 24 歲的人類角膜的透射比變量曲線圖。
2. Waxler, M., 及 V. M. Hltcens, 「光學輻射與視力健康」(Boca Raton: CRC Press, 1986) P.19, 圖 5 一個 25 歲人類水晶體的透射比變量曲線圖。

警告：可抗紫外線隱形眼鏡不是用來取代保護性的可抗紫外線眼鏡，像是紫外線護目鏡和太陽眼鏡，因為它不能完全蓋住眼睛和眼睛週圍的部位。患者應依指示繼續使用可抗紫外線眼鏡。

作用：在含水的情況，“酷柏”佰美視雙週拋軟式隱形眼鏡放在人的角膜上，其作用就像一個折射傳導體，使光線集中於視網膜。

“酷柏”佰美視雙週拋軟式隱形眼鏡的可見淡藍色，當在未配戴時可以清楚看見鏡片。

“酷柏”佰美視雙週拋軟式隱形眼鏡(-2.00D ~ -10.00D) 能阻斷 70% 的紫外線 A 和 96% 的紫外線 B。“酷柏”佰美視雙週拋軟式隱形眼鏡對紫外線的阻隔力會隨著鏡片厚度增加(請參閱上方之穿透曲線圖)。

註：長時間曝露於紫外線輻射是白內障的風險因子之一。曝露是依據因子數而定，例如環境條件(高度、地理環境、雲層厚度)和個人因素(戶外活動的長度和性質)。可抗紫外線隱形眼鏡有助防護有害的紫外線輻射，但未進行過臨床研究，以顯示配戴可抗紫外線隱形眼鏡可減少發生白內障或其他眼疾的風險。若要獲得進一步資訊，患者應該洽詢其眼科專業人員。

禁忌症(不使用的理由)：

患者倘若有下列情況，**不應使用**“酷柏”佰美視雙週拋軟式隱形眼鏡：

- 前眼室急性或亞急性炎症，或感染。
- 任何眼睛疾病，外傷，或影響角膜，結膜，或眼瞼的異常狀況。
- 嚴重淚液分泌不足(乾眼症)。
- 角膜感覺遲鈍(角膜敏感性減低)。
- 任何可能影響眼睛或因配戴隱形眼鏡而惡化的全身性疾病。
- 任何可能會感染眼睛，或可能因配戴隱形眼鏡而變嚴重的系統疾病。
- 可能因配戴隱形眼鏡或使用隱形眼鏡溶液引起眼球表面惡化或其附屬器官的過敏反應。
- 對保養隱形眼鏡的溶液中的任何成份過敏，像是水銀或 thimerosal 或 chlorhexidine。
- 使用禁忌的藥物，包括眼睛的藥物。
- 患者有(1)再發性眼疾或眼瞼感染的病史，(2)戴隱形眼鏡有副作用產生，(3)對戴隱形眼鏡會產生不能忍受或視覺不正常的情形。
- 患者不依照隱形眼鏡的保養法、消毒法、配戴的限制、配戴的時程，以及不定時去眼睛照護業者看診。
- 因為年齡、體弱或其他心理或生理的情況，或因為不利的工作環境或生活環境，使得患者沒有能力或不願意去了解或配合任何警告、處方、限制或指導。除此之外，只需要視力矯正的患者(1)不願或不能遵守推荐的照護系統，或(2)無法戴上或拿下提供給他們的鏡片。

注意事項：

- 某些職業或某些情況可能不適合戴隱形眼鏡，這種人需要保護裝備。
- 為了將隱形眼鏡的污染，或將近生理的傷害減到最低，配戴隱形眼鏡者應該避免環境的煙薰、香菸、灰塵、蒸汽、和多風的情況。

- 建議使用滅菌之隱形眼鏡保護溶液。如果有特殊的配戴者對防腐劑過敏則應使用滅菌不含防腐劑之溶液，並依標籤說明丟棄過期之溶液。
- 眼部因隱形眼鏡的刺激、感染或受損而受到的傷害，可能是因鏡片的污染造成的，配戴者應小心防範化妝品、化妝水、肥皂、乳霜、噴髮膠或除臭劑接觸到鏡片。
- 配戴者請勿使用拔毛鉗或其他工具從鏡片容器內拿出鏡片。鏡盒內容物應倒在手中。
- 應讓配戴者了解移除眼中鏡片之正確方法，並確配戴者能正確操作。
- 在配戴“酷柏”佰美視雙週拋軟式隱形眼鏡時，不應使用螢光黃，鏡片會吸收這種染料而退色。倘若鏡片在配戴者的眼睛裏接觸到螢光黃，則應以可使用在眼內的無菌生理食鹽水溶液徹底沖洗，且在至少一小時後重新配戴鏡片。
- 為了預防污染及避免眼睛受傷，在每次鏡片消毒的周期時，在取出鏡片後的鏡盒應該以新鮮潤濕液清洗並保持鏡盒空氣乾燥
- 服用口服避孕藥者能會改變視力，或配戴隱形眼鏡時對鏡片的容忍度會改變，配戴者應依規定注意。
- 配戴者應告知眼科專業人員他們配戴隱形眼鏡，用藥之前並諮詢醫師。
- 某些藥品（像是抗組織胺、解充血藥、利尿劑、肌肉鬆弛劑、鎮定劑，以及情緒疾病藥）可能會造成眼部的乾燥，增加鏡片的察覺感，或視力模糊，倘若有這種情況存在，應該開立適當補救措施的處方，依照嚴重的程度而定，這種措施包括使用軟性隱形眼鏡專用的潤滑劑，或在使用此種藥物時，暫時中斷隱形眼鏡的配戴。
- 為了更能確保配戴者眼睛的健康，必須定期去看眼科專業人員。配戴者應該被教導要有遵守後續看診的日程表。
- 眼科專業人員應該警告配戴者，每日配戴應在睡前拿下鏡片。

副作用：

請告知配戴者，配戴隱形眼鏡可能發生下列問題：

- 眼睛可能出現灼燒感、刺痛及/或癢。
- 隱形眼鏡戴久後可能比剛配戴時不舒服。
- 可能感覺眼睛裏有東西（外物、劃傷的部位）。
- 由於周圍的滲透、周圍的角膜潰瘍及角膜侵蝕可能造成暫時性損傷。也可能觀察到其他生理上的不正常，如局部或全面性的水腫，角膜新生血管化，角膜玷污、感染，眼瞼軟骨不正常，虹膜炎，結膜炎及少量可接受臨床症狀。
- 可能有淚水分泌過多，不正常的眼睛分泌物，或眼睛發紅。
- 如果鏡片磨損或戴得太久，可能會發生視力不良；出現光暈或畏光，或眼睛乾燥。

如果配戴者說出任何問題，包括但不限於前述，便應接受指導立刻拿掉鏡片，然後：

- 如果不舒服或問題停止，配戴者應仔細看一看鏡片。
- 如果鏡片上有污物、眼睫毛或其他異物，患者應該接受指示做下列事情：
 - 如果配戴者為拋棄式配戴計劃，則他就應該拋棄鏡片，換一副新的。
 - 如果配戴者為定期更換配戴計劃，且鏡片顯然並沒有受損，則配戴者應該清潔、消毒鏡片，並重新戴上。
- 如果鏡片受損，配戴者不應該再戴，應將之拋棄，再換一副新的。
- 如果配戴者的問題持續存在，不應把鏡片再戴回眼睛裏，而應立刻聯絡其眼科專業人員，由眼科專業人員決定是否必須檢查、治療，或不延誤地轉診。
- 配戴者必須被告知，若發生任何前述之症狀，可能是嚴重的狀況，像是感染、角膜潰瘍、角膜的新生血管化，或可能出現虹膜炎。配戴者應該立刻尋求眼科專業人員鑑定問題，並且立刻治療，以避免眼睛嚴重受損。較不嚴重的反應，像是擦傷、上皮污染，以及細菌性結膜炎，應該施以適當的治療，以避免併發症。

配戴計劃：

建議配戴者應每年去看眼科專業人員兩次，或兩次以上。眼科專業人員應該決定適當的配戴計劃和替換計劃，以提供給配戴者。

每日配戴：每日配戴的配戴者有一種傾向，那就是一開始的時候，會過度配戴，因此眼科專業人員應該強調，重要的是這種配戴者須遵守適當的最初配戴計劃表。眼科專業人員應該決定適當的配戴計劃和更換計劃，並提供給配戴者。

鏡片保養指示：

眼科專業人員應該就鏡片的保養和處理，提供配戴者適當的和充份的指導及警告，眼科專業人員也應該依據特定的鏡片配戴計劃和所選擇的保養系統，特定的產品指示，和配戴者的特性，為每一位配戴者推薦適當和足夠的程序及產品。

用拋棄式配戴計劃的配戴者：眼科專業人員應該和配戴者一起了解拋棄式鏡片不需要清潔或消毒，配戴者拿下鏡片之後一定要拋棄，並且換上新的。有關緊急鏡片保養的完整資訊，請參考使用拋棄式配戴計劃的配戴者資訊手冊，緊急鏡片保養不適用於每日配戴式計畫中受損的鏡片。

使用更換計劃的配戴者：有關“酷柏”佰美視雙週拋軟式隱形眼鏡的保養、清潔和消毒之完整資訊，應參考使用更換計劃的配戴者資訊。

乾燥鏡片的保養

軟式鏡片如果離開眼睛，又曝露在空氣中一段時間，可能會變得乾又脆，必須重新滋潤。如果鏡片固著於一個平面上，像是台面上，在處理之前須先用無菌的生理食鹽水溶液沖洗。

眼科專業人員應該和配戴者一起了解下列重新滋潤鏡片的資訊：

- 小心處理鏡片
- 將鏡片放貯存盒中，將鏡片浸在推荐的沖洗液中至少一小時，直到鏡片恢復柔軟狀態。
- 用推荐的保養清潔、消毒，並重新滋潤鏡片。
- 浸泡後如果鏡片真的變軟了，在接受眼眼科專業人員的檢查之前，不應戴上。

沾黏鏡片的保養：

如果鏡片黏在眼球上（或不再移動），應該指示配戴者直接滴幾滴推荐使用的潤滑劑，或隱形眼鏡護理液到眼睛裏，等到鏡片能夠在眼睛裏自由移動。如果幾分鐘以後鏡片仍然沒有移動，配戴者應該立刻諮詢其眼科專業人員。

眼科專業人員使用的試戴片：所有的鏡片於開封試用後必須予以丟棄。

如何供應：每個“酷柏”佰美視雙週拋軟式隱形眼鏡是裝在附有食鹽緩衝液的容器裏面，並於消毒後供應的，有些容器以多層式包裝整理，且每一包裝外都註明鏡片的製造批號、屈光度數、基弧以及序號、直徑、軸度、散光度數以及到期日。

包裝：1片/盒，2片/盒，3片/盒，6片/盒

製造廠名稱：CooperVision Caribbean Corporation






製造廠地址：500 Road 584, Lot 7, Amuelas Industrial Park Juana Diaz, PR 00795, USA

藥商名稱：酷柏光學有限公司

藥商地址：臺北市中山區新生北路一段66號7樓

**BIOMEDICS® 55 (ocufilcon D)
Soft (Hydrophilic) Contact Lenses
Package Insert**

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eye-care practitioner but should be made available to patients upon request. The eye-care practitioner should provide the patient with the appropriate patient instructions and/or patient information booklet which pertains to the patient’s prescribed lenses.

Symbol	Description
	CAUTION: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a licensed practitioner.
	See Instruction Leaflet
	Use by date (expiration date)
	Batch code
	Sterile using steam heat

INDICATIONS (USES):

BIOMEDICS® 55 UV Asphere (Ocufilcon D) Soft contact lenses is indicated for the correction of visual acuity in persons with non-aphakic, non-diseased eyes which manifest myopia (nearsighted), hyperopia (farsighted), or astigmatism correction lower than –2.00 diopters that does not interfere with visual acuity . It is a daily wear and 2 weeks replacement.

DESCRIPTION:

The lens material for BIOMEDICS 55 UV ASPHERE (ocufilcon D) Soft Contact Lens is a random copolymer of 2-hydroxyethylmethacrylate and methacrylic acid. The BIOMEDICS 55 UV ASPHERE (ocufilcon D) Soft Contact Lenses contain visibility blue tint from edge to edge using (VAT Blue 6) which is added in monomer prior to polymerization to make the lens more visible for handling. The BIOMEDICS 55 UV ASPHERE (ocufilcon D) Soft Contact Lenses contain a benzophenone UV absorbing monomer which is used to block UV radiation. The BIOMEDICS 55 UV ASPHERE (ocufilcon D) Soft Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

BIOMEDICS 55 UV ASPHERE (ocufilcon D) Soft contact lenses is hemispherical shells of the following dimensions:

Diameter:	12.0 mm to 18.0mm
Base Curve:	6.50 mm to 12.80 mm
Center Thickness:	0.025 mm to 0.40 mm,
Powers:	Plano to – 10.00D

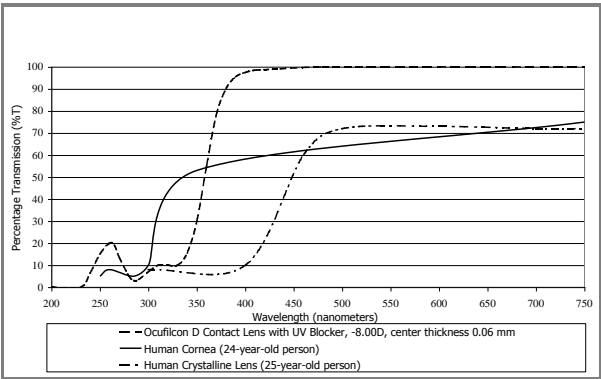
The physical parameters of the lens are as follows:

Refractive Index:	1.41
Surface Characteristics:	Hydrophilic
Water Content:	55.0%
Oxygen permeability (Dk)	19.6 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg at 35°C
Light Transmittance:	97.0%

Design

The BIOMEDICS 55 UV ASPHERE (ocufilcon D) Soft Contact Lens is hemispherical flexible shells which cover the cornea and may cover apportion of the adjacent sclera.

This is the transmittance profile of –8.00D ocufilcon D hydrophilic contact lens with UV blocker versus a human cornea and a human crystalline lens



1. Lerman, S., *Radiant Energy and the Eye* (New York: MacMillan, 1980), p. 58, Figure 2-21. Transmittance profile of the human cornea of a 24-year-old person.
2. Waxler, M., and V. M. Hitchens, *Optical Radiation and Visual Health* (Boca Raton: CRC Press, 1986), p. 19, Figure 5. Transmittance profile for the human crystalline lens of a 25-year-old person.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear, such as UV-absorbing goggles or sunglasses, because they do not completely cover the eye and surrounding area. Patients should continue to use UV-absorbing eyewear as directed.

ACTIONS:

In its hydrated state, the **BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens, when placed on the human cornea, acts as a corrective refracting medium to focus light rays on the retina.

The visibility-tinted **BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens, allows the lens to become readily visible to the wearer when it is not on the eye.

The thinnest **BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens,(-2.00 to -10.00 D) blocks 70% of UVA radiation and 96% UVB radiation average across the spectrum. The radiation blockage of the Biomedics UV lenses will increase for thicker lenses (Please refer to accompanying transmittance curve graph).

NOTE: Long-term exposure to ultraviolet radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors, such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of the outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult their eye-care practitioners for more information.

CONTRAINDICATIONS (REASONS NOT TO USE):

Patients **SHOULD NOT USE BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens when any of the following conditions exist:

- Acute and subacute inflammation or infection in the anterior chamber of the eye.
- Any eye disease, injury, or abnormality affecting the cornea, conjunctiva, or eyelids.
- Severe Insufficiency of lachrymal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or by using contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal or chlohexidine, in a solution which is to be used to care for the lens.

- Use of a medication that is contraindicated, including eye medications.
- Patient history (i.) of recurring eye or eyelid infections, including sties; (ii.) of adverse effects associated with contact lens wear; or (iii.) of intolerance or abnormal ocular response to contact lens wear.
- History of patient non-compliance with contact lens care and disinfection regimens, wearing restrictions, wearing schedule, or follow-up visit schedule.
- Patient inability or unwillingness, because of age, infirmity, or other mental or physical conditions, or because of an adverse working or living environment, to understand or comply with any warnings, precautions, restrictions, or directions. Additionally, patients who require only vision correction and (i.) who would not, or could not, adhere to a recommended care system for lenses; or (ii.) who are unable to place or remove lenses should not be provided with them.

PRECAUTIONS:

- Contact lens wear may not be suitable for those in certain occupations, or, in other instances, such persons may require protection equipment.

- In order to minimize the likelihood of lens contamination or of physical trauma to the cornea, lens-wearing patients should avoid environmental fumes, smoke, dust, vapors, and windy conditions.

- Recommend to use of sterile lens-care solutions. If a particular patient is allergic to preservatives, that patient should use sterile non-preserved solutions and should discard such solutions after the time specified in their label directions.

- Eye injury from irritation or infection and damage to contact lenses may result from lens contamination. Patients should take care to prevent cosmetics, lotions, soaps, creams, hair sprays, or deodorants from coming into contact with their lenses.

- Tweezers or other tools should not be used by patients to remove lenses from lens containers; rather, the contents of a lens container should be poured into the hand.

- Practitioners should instruct their patients as to the proper manner to promptly remove their lenses, and patients should be able to demonstrate the ability to do so.

- Fluorescein should not be used while **BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens is on the patient’s eye. The lenses absorb this dye and become discolored. In the event fluorescein does come in contact with the lenses while they are on the patient’s eye, the eyes should be flushed thoroughly with a sterile saline solution recommended for in-eye use, and new lenses should be inserted only after at least one hour.

- After removal of the lenses from the lens case, to prevent contamination and to help avoid serious eye injury, the patient should always empty and rinse the lens case with fresh rinsing solution and allow it to air-dry between each lens disinfection cycle.

- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.

- Contact lens-wearing patients should be instructed to inform their physicians that they wear contact lenses; further, patients’ physicians should consult their eye-care practitioners before using any medication in the eye.

- Certain medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and medications for motion sickness) may cause dryness of the eye, increased lens awareness, or blurred vision. Should these conditions exist, proper remedial measures should be prescribed. Depending on the severity, such measures could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medications are being used.

- As with any contact lens, follow-up visits are necessary to better ensure the continuing health of the patient’s eyes. The patient should be instructed as to a recommended follow-up schedule.

- Practitioners should caution their patients wearing **BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens on a daily-wear schedule to remove their lenses before sleeping.

ADVERSE EFFECTS:

Patients should be informed that the following problems may occur when they wear contact lenses:

- The eye may be painful or may burn, sting, or itch.
- There may be less comfort than when the lens was first placed on eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, infection, tarsal abnormalities, iritis, and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering (tearing), unusual eye secretions, or redness of the eye.
- Poor visual acuity; rainbows or halos around objects; photophobia; or a feeling of dryness (dry eyes) may also occur if the lenses are worn continuously or for too long a time.
-

If a patient reports any problems, including, but not limited to, the foregoing, he or she should be instructed to remove his or her lenses immediately. Then:

- If the discomfort or problem stops, the patient should look closely at the lens.
- If the lens has dirt, an eyelash, or other foreign body on it, the patient should be instructed as follows:
 - If the patient is in the Disposable Wear Program, he or she should dispose of the lens and replace it with a fresh, new lens.
 - If the patient is in the Scheduled Replacement Program, and if the lens appears undamaged, he or she may clean, disinfect, and reinsert the lens.
- If the lens is or appears in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and insert a fresh, new lens on the eye.
- If the patient’s problem continues, the patient SHOULD NOT put the lens back on the eye; but rather he or she should immediately contact his or her eye-care practitioner or a physician, who must determine the need for examination, treatment, or referral without delay.
- The patient should be advised that when any of the aforementioned symptoms occur, a serious condition such as infection, corneal ulcer, corneal neovascularization, or iritis may be present and may progress rapidly. The patient should seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage. Less serious reactions, such as abrasions, epithelial staining, and bacterial conjunctivitis, should be treated appropriately to avoid complications.

WEARING SCHEDULES:

It is recommended that a contact lens-wearing patient see his or her eye-care practitioner twice each year or, if so directed, more frequently. The practitioner should determine the appropriate wearing schedule and replacement schedule, which he or she should provide to the patient.

Daily Wear: There may be a tendency for the daily-wear patient to overwear the lenses initially. Therefore, practitioners should stress to these patients the importance of adhering to a proper initial daily wearing schedule. The practitioner should determine the appropriate wearing schedule and replacement schedule, which he or she should provide to the patient.

LENS CARE DIRECTIONS:

Eye-care practitioners should provide their patients with appropriate and adequate instructions and warnings for lens care and handling, and practitioners should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens-wearing schedule and care system selected by the practitioner, the specific instructions for such products, and the particular characteristics of the patient.

For patients in the Disposable Wear Program: Eye-care practitioners should review with patients that no cleaning or disinfection is needed with disposable lenses. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

For complete information concerning emergency lens care, refer to the Patient Information Booklet for patients in the Disposable Wear Program. Emergency lens care does not apply to lenses worn on a daily-wear basis.

For patients in the Scheduled Replacement Program: For complete information concerning the care, cleaning, and disinfecting of **BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens, patients should refer to the Patient Information Booklet for the Scheduled Replacement Program.

CARE FOR A DEHYDRATED LENS:

If a soft contact lens is off the eye and is exposed to air for a significant period of time, it may become dry and brittle and need to be re-hydrated. If the lens is adhering to a surface such as a counter top, apply sterile saline before handling the lens.

Eye-care practitioners should review the following information on re-hydrating the lens with the patient:

- Handle the lens carefully.
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state.
- Clean and disinfect and re-hydrate lens using a recommended lens-care system.
- If the lens does not become soft after soaking, the lens should not be used until it is examined by the eye-care practitioner.

CARE FOR A STICKING LENS:

If the lens sticks (or stops moving), the patient should be instructed to apply several drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before attempting to remove it. If non-movement of the lens continues after several minutes, the patient should **immediately** consult with his or her eye-care practitioner immediately.

PRACTITIONER FITTING SETS:

All lenses which have been opened must be discarded after each fitting.

HOW SUPPLIED:

Each **BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens is supplied sterile in a container with a normal buffered saline solution. Several containers are packaged in a multi-pack arrangement, each of which is marked with the manufacturing lot number of the lens, the dioptric power, the base curve or series, the diameter, the axis, the cylinder and the expiration date.

Package : 1 lens/box, 2 lenses/box, 3 lenses/box, 6 lenses/box

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing **BIOMEDICS® 55** UV Asphere (Ocufilcon D) Soft contact lens or experienced with the lenses should be reported



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Juana Diaz, PR 00795, U.S.A

配戴隱形眼鏡操作方式暨注意事項

【警告】

隱形眼鏡為直接配戴於眼角膜上之醫療器材，若不遵照鏡片使用方法或不遵守使用上的注意事項，會造成角膜潰瘍、角膜炎(含感染性角膜炎)、角膜浸潤、角膜糜爛、角膜水腫、結膜炎(含巨大乳突性結膜炎)、虹彩炎等傷害。這些傷害中，如果不盡快治療而置之不理，有可能致使眼睛失明。為了安全又正確地使用隱形眼鏡，務必詳閱原製造廠所提供之使用說明書，文字或內容文章有不清楚的地方，務必向眼科醫師詢問，並請妥善保留原製造廠所提供之使用說明書。

壹、軟式隱形眼鏡的處理方式

一、注意事項：

1. 初戴者，可從每天戴 4 至 6 小時開始，每日增加 2 小時。
2. 若有明顯不適之情形應儘早回診檢查，一切正常則應於一星期後回診。
3. 戴上鏡片後再化妝，摘下鏡片後再卸妝。
4. 必須知道清潔液、生理食鹽水、保存液、酵素液或酵素片的功用，開瓶後保存期限以仿單內之規定為準。

清潔液-清洗鏡片，生理食鹽水-沖洗鏡片，保存液-浸泡及消毒鏡片，酵素液-去蛋白。

5. 瓶蓋要朝上或側放，不得朝下擺放，以避免污染。
6. 固定先摘戴一眼，再摘戴另一眼(如先右後左)，以免鏡片左右顛倒。
7. 摘鏡片的食指、拇指指甲須剪短，以免摘鏡片時傷到眼球或隱形眼鏡。
8. 戴鏡片時要先分辨鏡片的正(如碗狀)反(如碟狀)面。
9. 所有與隱形眼鏡相關的物品，如鏡片、水盒或藥水等，不得擺放在潮濕處，如浴室。

二、鏡片配戴方法：

1. 用中性肥皂清洗雙手，再擦乾雙手。
2. 將鏡片置於右手食指指腹尖端，正面朝上。
3. 以右手中指拉開下眼皮，左手中指拉開上眼皮。
4. 兩眼直視前方，再將鏡片移至黑眼珠上。
5. 確認鏡片已戴上，輕轉眼球，再慢慢鬆開雙手。
6. 若鏡片掉落地面或桌面，用姆指及食指抓取其邊緣即可取起。須重新洗乾淨、浸泡、消毒後再戴上(確定正反面)。

三、鏡片卸取方法：

1. 眼睛正視前方。
2. 以右手中指拉開下眼皮，左手中指拉開上眼皮。
3. 以右手拇指及食指指腹尖端，輕置於鏡片下緣。
4. 兩指合攏，輕輕取下鏡片。
5. 若鏡片掉落地面或桌面，用姆指及食指抓取其邊緣即可取起。

四、鏡片的清洗及保養方式：

1. 將鏡片放在左手掌心，清潔液搖勻後，倒一或二滴在鏡片上。
2. 以右手食指指腹，將鏡片呈放射狀向外搓揉 20 秒至 30 秒左右。
3. 以生理食鹽水將鏡片沖洗乾淨。
4. 將洗淨的鏡片分別置入水盒中(約七分滿的新鮮保存液)，浸泡 6 小時以上，才可取戴。

五、水盒的保養方式：

1. 每次使用後，以清水沖洗乾淨，再用力甩乾後放置陰乾。
2. 一星期消毒一次。用牙刷沾點"洗碗精"刷洗水盒凹槽處，再用熱水沖淋乾淨、放置陰乾即可。建議每三個月換新水盒。

六、酵素片的使用方法：

1. 水盒中注入生理食鹽水，左右各投入一片酵素片，待其完全溶解。
2. 事先以清潔液清洗鏡片，再用生理食鹽水沖淨。
3. 浸泡在酵素溶液中約 30 分鐘(不可超過 2 小時)。
4. 取出鏡片，用清潔液清洗，再用生理食鹽水沖淨。
5. 浸泡在新鮮的保存液中 6 小時以上，才可取戴。

貳、透氧硬式隱形眼鏡的處理方式

一、注意事項：

1. 請依照醫師指示定期回診。
2. 瞭解清潔液、生理食鹽水、保存液及酵素液的功用，並依照仿單內之方法進行清洗及消毒。
3. 瓶蓋要朝上或側放，不得朝下擺放或觸摸瓶口，用完立即蓋妥，以避免細菌污染。(藥水開封後限使用一個月，過期請換新)
4. 所有與隱形眼鏡相關的物品，如鏡片、水盒或藥水，不得擺放在潮濕處，如浴室。
5. 食指、拇指指甲須剪短，以免摘鏡片時傷到眼球或隱形眼鏡。

二、鏡片配戴方法：

1. 用中性肥皂清洗雙手，再用擦手紙將手擦乾。

2. 將鏡片置於右手食指尖端指腹，正面朝上。
3. 以右手中指拉開下眼皮，左手中指拉開上眼皮，將鏡片輕輕放角膜中央。
4. 確認鏡片已戴上，再慢慢鬆開雙手。

三、鏡片卸取方法：

〈雙手摘法〉

1. 眼睛直視鏡中。
2. 右手中指平按著下眼皮，固定鏡片下緣(勿太用力，以避免眼皮外翻)；左手中指平按著上眼皮，固定鏡片上緣。
3. 眼皮輕眨，鏡片會向下翻落。(注意以手接住)
4. 鏡片掉落地面或桌面上，切勿直接抓取，以免磨損鏡片表面。應該以紙片插入鏡片下面，或加水使鏡片浮起，再行撈起。

〈單手摘法〉

1. 將下巴稍為縮緊，眼睛張大，正視鏡中。
2. 以食指固定上眼皮，同一手中指固定下眼皮。(若眼睛無法張大，可用食指及中指將上、下眼皮稍微撐開)
3. 兩隻手指往外眼角斜上方拉(要有"緊"的感覺)，此時眼睛持續張大，再往鼻樑的方向看，鏡片會自然的被"推擠"出來。(注意以另一手接住)

〈吸棒摘法〉

1. 眼睛正視前方。
2. 以左手食指將上眼皮撐開，右手中指將下眼皮拉下。
3. 擠壓吸棒尾端，將吸盤覆上鏡片表面，放鬆擠壓以形成負壓將鏡片吸住。摘出鏡片後，再擠壓吸棒尾端，可除去負壓，取下鏡片。
4. 請務必確定鏡片位置，才可將吸棒吸附上去，以避免吸到眼球。
5. 吸棒摘取鏡片的方式很簡單，但請不要過度依賴它，最好學會徒手摘。

四、鏡片移位的處理方法：

1. 正視前方，眼球不要亂轉。
2. 用手摸眼皮或將眼皮撥開，確定鏡片的位置。(例：右下角)
3. 眼睛先往鏡片相反的方向看。(例：左上角)
4. 手指抵著鏡片外緣(右下角外)，眼睛看回鏡片原先的方向(右下方)。
5. 鏡片回到黑眼球中間，才可摘下鏡片。
6. 若鏡片無法以上述方式移回黑眼珠，待確定位置後可用吸棒吸取。

五、隱形眼鏡水盒的保養方式：

1. 每次使用後，用自來水沖洗，再用力甩乾後放置陰乾。
2. 一星期消毒一次。用牙刷沾點"洗碗精"刷洗水盒凹槽處，再用熱水沖淋乾淨再放置陰乾。建議每三個月換新水盒。

* 另有高溫消毒及雙氧水消毒法，以遵照仿單之規定為準。

【禁忌及禁止】

配戴隱形眼鏡者，需依照當下的眼睛或身體的疾病、生活習慣或生活環境的情況，有可能需暫時停止使用隱形眼鏡。請務必經過眼科醫師的診察，確認無礙於疾病及環境後，再使用隱形眼鏡。

禁忌：●前眼部急性或亞急性發炎●眼睛感染●葡萄膜炎●眼瞼異常●角膜知覺低下●角膜上皮缺陷●乾眼及淚管缺陷●過敏●長時間生活在乾燥環境●長時間生活在粉塵、藥品等環境●其他不適合配戴隱形眼鏡者

【注意】

- 隱形眼鏡，請於醒著的時候使用，**睡前請摘下**。
- 屬每日拋棄式者，請每天更換新的鏡片(一旦摘下的鏡片，必須拋棄，不要重複配戴)。
- 其他型式者，請確實遵照原製造廠**所提供之使用說明書進行清洗、清潔、保存、拋棄**。
- **當配戴中鏡片破損時，請盡快找眼科醫師診治。**
- **請不要使用有破損的鏡片。**
- **請遵照鏡片更換頻率。**
- **請遵照鏡片配戴時間，不要逾時配戴。**
- 隱形眼鏡配戴時間因個人體質而不同，請務必遵照眼科醫師指示。
- **請定期做眼睛檢查。**
- **當眼睛感到異常時，請盡快向眼科醫師診治。**

【戴隱形眼鏡的危險】

在正確使用隱形眼鏡之下，仍然有可能使角膜內皮細胞減少等生理變化，或因戴隱形眼鏡的關係，鏡片使眼睛氧氣供應量降低，造成角膜上皮受傷或角膜新生血管等眼睛傷害的危險。為不致產生更嚴重的眼科疾病，有任何不適，請及早尋找眼科醫師診治，並定期檢查。