INSTRUCTIONS FOR USE

Dvali Kerabow Ring

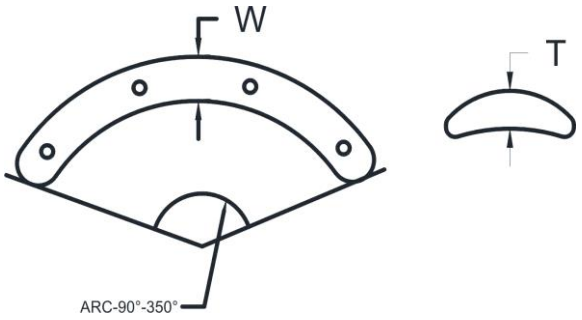
Device Description

KERABOW - Corneal segments Implants are an ophthalmic medical device designed for the reduction or elimination of myopia and astigmatism in patients with keratoconus (KC) so that their functional vision may be restored and the need for a corneal transplant procedure can potentially be deferred. When placed in the corneal stroma, outside of the patient's central optical zone, the product reduces the cone by flattening the cornea and for non-central keratoconus, repositions the cone centrally. Corneal segments are designed to be placed in the periphery of the cornea, at approximately two-thirds depth, and are surgically inserted through a small radial incision in the corneal stroma. The placement of the incision will be typically temporal at the axis of positive cylinder; however, may vary depending on the location of the cone and the amount of keratoconus present in the specific eye to be treated. The Corneal segments are to be placed equidistant on each side of the incision.

The KERABOW Corneal segment Implants have an arc length from 90 degree to 325 degree. They are manufactured from Polymethyl methacrylate (PMMA) and are available from 0.150 mm to 0.300 mm thickness, in 0.050mm increments. In order to reduce the myopia and the irregular astigmatism induced by keratoconus, two Corneal segments may be implanted depending on the patient's preoperative manifest refraction spherical equivalent (MRSE), the orientation of the cone and the degree of asymmetric astigmatism. The product is designed with a fixed outer diameter and width. The Corneal segments have two positioning holes, located at each end of the segment, to aid in surgical manipulation.

Product Technical Specification

Model	Arc Angle	Thickness µm	Width mm	Drawing	Other features
KCR-Deg- Th	90°-350°	150-450	0.60		Variable Arc length Thickness



Dvali KERABOW

INSTRUCTIONS FOR USE

INDICATIONS:

Dvali KERABOW- Corneal segments segment Implants are an ophthalmic medical device designed for the reduction or elimination of myopia and astigmatism in patients with keratoconus (KC) so that their functional vision may be restored and the need for a corneal transplant procedure can potentially be deferred.

INTENDED USER:

Ophthalmic surgeons only.

INTENDED PURPOSE:

Dvali kerabow, Corneal implants are intended for the reduction or elimination of Myopia and Astigmatism in patients with keratoconus, who are no longer able to achieve adequate vision with their contact lenses or spectacle's.

PATIENT TARGET GROUP:

Adult patients of age 18 years and above.

MODE OF ACTION:

When placed in the corneal stroma, outside of the patient's central optical zone, the product reduces the cone by flattening the cornea and for non-central keratoconus, repositions the cone centrally. Corneal segments are designed to be placed in the periphery of the cornea, at approximately two-thirds depth, and are surgically inserted through a small radial incision in the corneal stroma. The placement of the incision will be typically temporal at the axis of positive cylinder; however, may vary depending on the location of the cone and the amount of keratoconus present in the specific eye to be treated. The Corneal segments are to be placed equidistant on each side of the incision.
To reduce the myopia and the irregular astigmatism induced by keratoconus, two Corneal segments may be implanted depending on the patient's preoperative manifest refraction spherical equivalent (MRSE), the orientation of the cone and the degree of asymmetric astigmatism. The product is designed with a fixed outer diameter and width. The Corneal segments have two positioning holes, located at each end of the segment, to aid in surgical manipulation. Corneal segments are available for Optic zone diameter 5 mm and 6 mm.

Typical Treatment Nomogram (see diagram below).

The Corneal segments treatment nomogram for keratoconus is based on the clinical results from implanting the 0.350 mm, 0.400 mm and 0.450 mm thicknesses of segments in keratoconus patients. The Lower thickness is proposed to be used to treat those keratoconus patients who require only a minimal amount of corneal flattening and/or corneal stabilization, who are contact lens intolerant and who can no longer be effectively corrected with spectacles to restore their functional vision. The specific determination of which thickness of the corneal segments to implant is dependent upon the nomogram and several variables: the most significant being the patient's preoperative manifest refraction spherical equivalent, the location of the cone and the degree of asymmetric astigmatism present.

- The surgical technique for keratoconus is like the standard corneal segment surgical technique used for low myopia, except that the location of the incision is often placed temporally.
- Pachymetry is to be measured during surgery at the peripheral location of the entry incision. All patients shall have a corneal thickness of 450 microns or greater at the proposed incision site. The incision depth should be at 68% of the corneal thickness measured at the peripheral location of the entry incision.
- A temporal incision is typically used depending on the location of the astigmatism. Some corneal surgeons place the entry incision in the same meridian as the axis of positive cylinder.
  Note: Patients may be allowed to manually adjust the axis of cylinder at the Phoropter to achieve the clearest subjective image. This technique may work better than the Jackson cross-cylinder technique for patients with irregular astigmatism.
- An asymmetrical cone is treated with a thinner Corneal segment placed superiorly and a thicker Corneal segment placed inferiorly.
- Global and central cones are typically treated using two segments of the same thickness.
- The thicker Corneal segment is typically placed to correspond to the keratoconus cone (inferiorly) to lift the cone and produce the maximum flattening effect and the thinner Corneal segment is placed in the opposite corneal half (superiorly) to counterbalance the thicker segment and to flatten the rest of the corneal surface across the visual axis.

There are two primary criteria used in determining the surgical nomogram related to the use of Corneal segments Implants for keratoconus. The first criterion is whether the cone is centered or decentered (asymmetric cone).

INSTRUCTIONS FOR USE

Keratoconus, which is centrally present as determined by a topographical map, will require two corneal segments of the same thickness.
The thickness of the Corneal segments to be used is determined based on the preoperative spherical equivalent of less than or equal to -3.00 D or greater than -3.00 D. This would also apply to global keratoconus in which the keratoconus is central, but its circumference extends beyond 5.0 mm from the center.

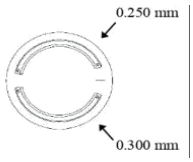
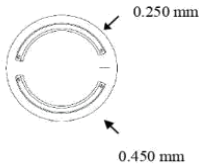
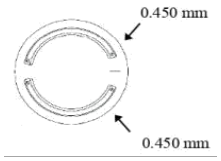
As for asymmetric cones, it is necessary to evaluate the degree to which the cone is decentered. This is done by reviewing a topographical map of the cornea. Moderate asymmetry exists when the cone is off-center in placement at the 3.0 mm ring on the topographical map. High asymmetric cones are typically 5.0 mm or more off-center, as exhibited on a topographical map. In each of these cases, two different thicknesses used will depend on whether the preoperative spherical equivalent is less than or equal to -3.00 D or greater than -3.00 D. The thicker Corneal segment is recommended to be placed inferiorly and the thinner Corneal segment is to be recommended be placed superiorly.

The recommended corneal segment placement and thickness nomogram to be used for keratoconus is presented below:

Recommended Corneal segment Placement Nomogram for Keratoconus	
Type of Keratoconus	Product Configuration
Asymmetrical Cone	Two Corneal Segments of different thicknesses implanted (One thinner Corneal segment placed superiorly – One thicker Corneal segment placed inferiorly)
Global Cone	Two corneal segments of the same thickness implanted (One Corneal segment Placed superiorly – One Corneal segment placed inferiorly)
Central Cone	Two corneal segments of the same thickness implanted (One Corneal segment Placed superiorly – One Corneal segment placed inferiorly)

Recommended corneal segment Thickness Nomogram for keratoconus		
Type of cone	Preop MRSE< 3.00 D	Preop MRSE> 3.00 D
Asymmetrical Cone: Moderate asymmetry High asymmetry	0.300 mm 0.350 mm/0.400 mm 0.400 mm	0.350 mm 0.400 mm/0.450 mm 0.450 mm
Global cone	0.400 mm / 0.400 mm	0.450 mm/0.450 mm
Central cone	0.400 mm / 0.400 mm	0.450 mm/0.450 mm

INSTRUCTIONS FOR USE

Diagram 1 Asymmetrical Cone-  	For patients with a preoperative MRSE ≤ 3.00 D, one thinner Corneal segment (e.g., 0.300 mm) is placed superiorly and one thicker Corneal segment is placed inferiorly (e.g.,0.350mm), temporal incision placement is used (9:00 for right eye and 3:00 for left eye).
Diagram 2 Asymmetrical Cone-  	For patients with a preoperative MRSE >3.00 D, one Corneal segment (e.g., 0.300 mm) is placed superiorly and one thicker. Corneal segment is placed inferiorly. (e.g., temporal incision used (9:00 for right eye and 3:00 for left eye)
Diagram 3 Global Cone/Central Cone  	For patients with a preoperative MRSE > 3.00D, two segments of the same thickness are placed – one segment is placed superiorly, and one segment is placed inferiorly, temporal incision. placement is used (9:00 for right eye and 3:00 for left eye).

INDICATIONS:

Corneal segments (Implants) are intended for the reduction or elimination of myopia and astigmatism in patients with keratoconus, who are no longer able to achieve adequate vision with their contact lenses or spectacles, so that their functional vision may be restored and the need for a corneal transplant procedure may potentially be deferred.

The specific subset of keratoconus patients proposed to be treated with Corneal segment.

Implants are those patients:

- Who have experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision daily with their contact lenses or spectacles.
- Who are 21 years of age or older.
- Who have clear central corneas.
- who have a corneal thickness of 450 microns or greater at the proposed incision site; and
- who have corneal transplantation as the only remaining option to improve their functional vision.

CLINICAL BENEFITS:

- The clinical benefit of the implantation of Corneal Ring Segment is to avoid or postpone Corneal Transplant.
- Corneal Ring Segments improves patient's visual acuity. Avoid spectacle dependence and use of uncomfortable hard contact lens.

SIDE EFFECTS:

Foreign Body Sensation
Corneal Thinning

RESIDUAL RISK:

Some patients may experience loss of contrast sensitivity post operatively.

INSTRUCTIONS FOR USE

CONTRAINDICATIONS:

Corneal segment (implants) for keratoconus is Contraindicated:

- In patients who have abnormally thin corneas or who have a corneal thickness of 499 microns or less at the proposed incision site.
- In patients with collagen vascular, autoimmune or immunodeficiency diseases.
- In pregnant or nursing women.
- In the presence of ocular conditions, such as recurrent corneal erosion syndrome or corneal dystrophy, that may predispose the patient to future complications; or
- In patients who are taking one or more of the following medications: Isotretinoin (Accutane1); amiodarone hydrochloride (cordarone2).
- In patients who have Fuchs' dystrophy or have suspect endothelial cell deficiency are not candidates for corneal segment Implants.

WARNINGS

- Some patients with large, dilated pupil diameters (≥7.0 mm) are predisposed to low light visual symptoms postoperatively and should be appropriately advised.
- The long-term effect of corneal segment Implants on endothelial cell density has not been established. Central endothelial cell density loss for myopic eyes implanted with 0.350 mm corneal segment implants was 1.4% ± 3.9%
- Patients who have the 0.400 mm or 0.450 mm corneal segment Implants should be monitored on a more frequent basis in order to detect peripheral endothelial cell loss and/or related corneal edema. These patients should be advised about the potential risk of developing peripheral endothelial cell loss and/or corneal edema, possibly requiring corneal transplantation, with potential unforeseen impact of peripheral endothelial cell loss on the success of future PKP.

ANNUALIZES PERCENT CHANGE IN ENDOTHELIAL CELL DENSITY,0.400 MM, AND 0.450 MM CORNEAL SEGMENT IMPLANTS

Region	Central	6.00 Peripheral	10.00 Peripheral
N	17	12	15
Mean ± SD (%/year)	-1.63% ± .79%	-2.22% ± 0.86%	-1.85% ± 0.56%
95% Confidence Interval (%/year)	-1.99%-1.26%	-2.71%: -1.73%	-2.13%: -1.56%

PRECAUTIONS

- Use of the vacuum Centring Guide subjects the eye to increased intraocular pressure. Continuous application of vacuum should be limited to 3 minutes or less and to no more than 750 m Bar. If it is necessary to reapply the Vacuum Centring Guide, wait 5 minutes to allow normal vascular perfusion of the eye to occur before re-establishing suction.
- Corneal segment Implants are not recommended in patients with systemic diseases likely to affect wound healing, such as insulin-dependent diabetes or severe atopic disease.
- It is critical that the corneal segment Implants are properly oriented during the surgical procedure so that the corneal segment are not left beneath the incision area in order to avoid potential wound healing issues. The alignment of the implanted corneal segments is to be verified against the placement marks made on the cornea at the beginning of the corneal segment implantation procedure. If the corneal segments are not properly oriented operatively, the segments should be immediately re-positioned.
- Some patients (7/334 or 2.1%) who received the 0.400 mm and 0.450 mm Corneal segment Implants for the treatment of myopia experienced a temporary decrease of two or more lines of BSCVA during the U.S. myopia trial. The BSCVA was 20/20 or better upon resolution for all patients and the BSVCA for all patients returned to within 2-8 letters of their preoperative BSCVA.
- It is recommended that the corneal thickness at the 6 mm to 9 mm optical zone be at least 350 microns to allow for an adequate amount of corneal tissue above the Corneal segment Implants.

INSTRUCTIONS FOR USE

- Corneal segment Implants are not recommended in patients with a history of ophthalmic herpes simplex or Herpes zoster.
- Corneal segment Implants are not recommended in patients who are taking sumatriptan (imitrex3) for migraine headaches.
- A temporary decrease in central corneal sensation has been noted in some patients.
- The safety and effectiveness of alternative refractive procedures or a corneal transplant procedure following the removal of Corneal segment Implants have not been established.
- Corneal segment Implants are intended for single use only; do not reuse or resterilize. In the event that different thicknesses of corneal segment Implants are used during a procedure, please discard the unused segments.
- The safety of corneal segment Implants for keratoconus have NOT been established:
  -In patients with progressive myopia or astigmatism, nuclear sclerosis or other crystalline lens opacity, corneal abnormality, or previous corneal surgery or trauma.
  -For patients under 21 years of age.
  -For corneas with a central thickness less than 480 microns, or peripheral thickness less than 570 microns; or
  - In long-term use.

PATIENT INSTRUCTIONS AND IDENTIFICATION CARD PATIENT INSTRUCTIONS

- If patients wear contact lenses, they should be instructed to stop wearing them 2-3 weeks before their preoperative examination in order to obtain an accurate refraction.
- Patients should be instructed on the importance of using all medications as directed.
- Patients should be instructed to use the night time eye shield as directed to avoid injuring their surgery eye during sleep.
- Patients should be instructed not to rub their surgery eye for the first six months after the procedure. This is important to promote proper healing of the incision.
- Patients should be instructed to avoid getting tap water in their surgery eye for the first few weeks following the procedure.
- Patients should be advised to avoid swimming in pools for the first week after the procedure. Lake and ocean swimming should be avoided for the first month. Protective goggles should be worn at all times when swimming
- Patients should be instructed to contact you immediately if they experience any pain, discomfort, have a sensation that something is in their eye or experience a change in their vision after the initial postoperative recovery period (typically 7 days). Patients should be Instructed to report any unusual symptoms that could be associated with prolonged topical steroid use, if applicable.

IDENTIFICATION CARD

A Patient Identification Card is enclosed in the KERABOW Implants product package. Please complete this card and provide it to the patient at the time of surgery. The Patient Identification Card is intended as an implant card to be kept in the patient's wallet.

CONFORMANCE TO STANDARDS

KERABOW - Corneal segment Implants have been designed, manufactured, and distributed in conformance with requirements of the Quality System management ISO 13485:2016 and other relevant ISO standards, and the Medical Device Regulation (MDR) 2017/745.

MEDICAL DEVICE REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as related to the Corneal segments Implant for keratoconus and that were not previously expected in nature, severity or incidence rate should be reported to Addition Technology immediately. This information is being requested from all surgeons in order to document potential long-term effects of placement of corneal segments. Physicians must report these events in order to aid in identifying any emerging or potential problems with Corneal segment Implants to www.exceloptics.net

HOW SUPPLIED

The KERABOW, Corneal segments Implant are supplied in a plastic case contained within a heat-sealed Tyvek peel pouch and terminally sterilized using Ethylene Oxide (EO). The contents of the pouch are sterile unless the package is opened or damaged.

INSTRUCTIONS FOR USE

RETURN GOODS POLICY

For information on returning any damaged product, contact your local representative or call Excel optics Pvt Ltd for return authorization and full policy information. All products returned to Excel optics Pvt Ltd must be accompanied by a Return Goods Authorization Number.

LIMITATION OF WARRANTY AND LIABILITY

EXCEL OPTICS (P) LIMITED accepts no liability for any injury suffered to patients as a result of:

- Any implantation method or technique used by a physician to implant the Dvali Kerabow Corneal Ring Implant.
- Any prescription, and use of the Dvali Kerabow for any Individual patient or patient's conditions.

Excel Optics (P) Limited, makes no expressed or implied. Warranties in connection with the sale of the Dvali Kerabow – Corneal Ring Segments.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE:

Summary of Safety and Clinical Performance (SSCP) of this device will be available on the EUDAMED website https://ec.europa.eu/tools/eudamed after notified body acceptance of SSCP.

Note: Because the Corneal Ring and the packaging materials are plastic, the Corneal Ring may pick up an electrostatic charge upon opening the package. The Corneal Ring should be carefully examined to ensure that particles have not been attracted to it.

Implantation of Corneal Ring should not be performed in patients under the age of 18.

CAUTION:

GOVERNMENT LAWS RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DISPOSAL

- Discarded Corneal Ring (used or unused) are classified as medical (clinical) waste that harbours a potential infection or microbial hazard and must be disposed of accordingly.
- Do not dispose of damaged or explanted device or its packing with household trash. Disposal of devices and their packaging is considered a biohazard.
- Follow local regulatory guidelines for disposing of medical devices and their packaging safely.

STORAGE CONDITIONS:

Store between 5°C to 40°C temperature.

EXPIRATION DATE:

- The expiration date on the lens package is the sterility expiration date.
- Do not use the Corneal Ring after the expiration date.

INSTRUCTIONS FOR USE

Symbols and their Explanations

EC REP	Authorized Representative in the European community		Do Not re-use
STERILE EO	Sterilized using Ethylene Oxide		Do not re-sterilize
40°C 5°C	Storage Condition between 5°C to 40°C		Keep away from sunlight
	Manufacturer		Consult Instructions for Use
LOT	Sterile Batch No		Keep Dry
UDI	Unique device identifier	MD	Medical Device
SN	Serial Number		Single sterile barrier system with protective packaging inside
#	Model Number		Expiry Date
	Do not Use If package is Damaged		Date of Manufacturer
IN	Country of Manufacture		Caution
UV	Ultraviolet		

EC REP

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