- If for any reason the device is removed from sterile condition and not implanted, the device must not be used and appropriately discarded on hospital waste.
- Implant identification labels supplied must be affixed to patient and/or hospital and/or surgeon files in order to allow tracing each individual device to its end user (patient) if necessary, as required by national and international regulations.

INSTRUCTIONS FOR USE:

Open the sealed box and remove sterilization pouch containing the device. Peel the pouch open and remove plastic case to sterile environment. Using aseptic technique hold device case and turn top counter clockwise to expose the Keraring segments. Carefully inspect the device under the surgical microscope magnification. Carefully remove the device from plastic container using specific Keraring handling forceps and implant it in the corneal stroma as per specific surgical technique.

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MEDIPHACOS
OPHTHALMIC PROFESSIONALS

KERARING - INTRASTROMAL CORNEAL RING SEGMENTS

PRODUCT INFORMATION AND INSTRUCTIONS FOR USE
Revision 01

WARNING! This device must only be implanted by an experienced eye surgeon trained in the implantation technique of this specific device.

DEVICE DESCRIPTION:
Keraring segments (device, implant) are precision implantable devices implanted in the human corneal stroma for the correction of morphological and refractive disorders. The device is manufactured from polymethylmethacrylate (PMMA), and is implanted in the corneal stroma as per specific surgical technique. The device acts upon the corneal tissue by altering its central curvature and shape, thus reducing or eliminating morphological irregularities and existing myopia and astigmatism. The device is composed of one or two semi circular segments of variable arc lengths, variable apical diameters, variable thickness, having a fixed triangular cross section of 600 micra base. Each ring segment tip has a 0.2mm diameter hole to facilitate manipulation and implantation.

INDICATIONS:
The correct indication for implantation of the Keraring requires a thorough evaluation of topographic and pachymetric conditions of the cornea, in addition to complete ophthalmologic examination. In general, implantation of the device may be considered in the following cases:

Myopias between -5.0 D. and -11.0 D.;
- Myopic astigmatism greater than -2.0 D.;
- Keratoconus in contact lens intolerant patients;
- Progressing keratoconus;
- Contact lens induced corneal warpage (Hartstein Syndrome);
- Astigmatism following penetrating keratoplasty;
- Corneal ectasia following Lasik;
- Astigmatism following radial keratotomy;
- Pellucid marginal degeneration.

CONTRA-INDICATIONS:
Implantation of Keraring must not be considered in the following conditions:

- Advanced keratoconus (keratometric reading steeper than 75.0 D.) and severe cone apex opacities;
- Hydrops;
- Post PKP, when graft is decentered;
- Severe atopic disease
- Presence of active infection, localized or systemic;
- Autoimmune or immunodeficiency diasease;
- Recurrent corneal erosion syndrome;
- Extensive corneal scaring.
- Corneal distrophy

WARNINGS:
- During clinical investigations, the following complications have been reported in a limited number of patients: Implant extrusion, implant migration, implant decentration, infection, undercorrection, overcorrection, visual symptoms (halos and reflex).
- The safety and effectiveness of Keraring implantation have been established when used as directed. However, visual rehabilitation may be unsatisfactory if this device is not used in accordance to guidelines herein listed, or if patient fails to receive proper post-operative care.
- Some patients with large dilated pupil diameters are predisposed to low light visual symptoms and should be appropriately advised.
- It is anticipated that spectacle correction or contact lens correction may still be necessary following implantation of this device, especially in diseased cornea patients.
- Under mesopic conditions, patients may experience some loss in contrast sensitivity at low spacial frequencies.
- The safety and effectiveness of alternative refractive procedures following implantation of the Keraring has not been established.

HOW SUPPLIED:
Each Keraring is presented sterilized by ethilene oxide in a plastic case sealed inside a sterilization pouch. Device identification labels are provided and indicate model number, device dimensions, implant serial number, and sterilization expiration date. Keraring patient identification card and a implant notification form to be returned to manufacturer are also provided.

PRECAUTIONS FOR USE AND STORAGE:
- Do not use after sterilization expiration date indicated on package.
- Single use only. Do not resterilize.
- This device must only be implanted by an experienced corneal surgeon trained in intrastromal corneal ring implantation techniques and management of related complications.
- Manipulating this device requires the use of the appropriate techniques and instrumentation. Any device damaged during handling should not be implanted.
- The correct selection of device dimensions for a specific patient depends on preoperative manifest refraction and the presence and extent of other corneal conditions, such as keratoconus. Refer to clinical guidelines and updated nomograms available from Mediphacos.
- Do not use if sterile pouch is found opened and/or damaged.
- The device dimensions and sterilization expiration date should be verified before opening the sterile pouch.
- Store at room temperature. Avoid high temperatures above 45º Celsius.