INSTRUCTIONS FOR USE
EndoArt® Corneal Artificial Endothelial Layer

Cat. No.: EARRXXYYZZZ

1. IMPORTANT

Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.

The device is provided STERILE. DO NOT RESTERILIZE.

DO NOT USE the device if the package is open or damaged, or if the expiration date has passed.

The device is intended for SINGLE-USE only.

2. DEVICE DESCRIPTION

EndoArt® is a dome shaped, optically clear, transparent, foldable implant, made of hydrophilic material designed to adhere to the posterior portion of the cornea.

EndoArt® specifications

Diameter (D)	6.0 - 8.0 mm
Curvature Radius (Rcv)	6.0 - 8.0 mm
Thickness (T)	0.03 - 0.05 mm
Power	0.00 ± 0.25D

3. INTENDED USE

The EndoArt® implant is intended for use as an endothelial keratoprosthesis in patients with chronic corneal edema.

4. CONTRAINDICATIONS

DO NOT USE the EndoArt® when any of the following conditions exist:

- Severely scarred cornea unfit for regular endothelial keratoplasty
- Band keratopathy
- Severe dry eye
- Phthisis
- History of corneal refractive surgery
- History of neurotrophic cornea
- History of persistent corneal erosion difficulties with epithelial re-growth (re-epithelization) not related to bullous keratopathy
- Limbal stem cell deficiency

5. WARNINGS

- Do not use the device if the expiration date specified on the label has passed.
- Do not use the device if its sterility appears to be compromised.
- Single-use only. Do not re-use, re-process or re-sterilize, all of which may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury, illness or death. Re-use, re-processing or re-sterilization also bears risk of contamination to the device and/or patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Eye rubbing after implantation may lead to implant detachment. Patient should be instructed to avoid touching/rubbing the eye during the first month after implantation. Transparent eye shield wear is recommended.
- Instruct the patient to refer the physician in the event of any sudden pain, decrease in vision, redness or secretion from the eye following the implantation.

6. PRECAUTIONS

- Carefully inspect the device prior to use, to verify that it has not been damaged and that its size, shape and condition are suitable for the intended procedure. DO NOT use if product appears to be damaged.
- DO NOT use the device if the package has been opened, as sterility may be compromised.
- Only physicians trained in performing corneal surgical ophthalmic procedures should use EndoArt®, after undergoing learning the methodology of implanting EndoArt® and obtaining certification.
- EndoArt® implantation should be in an environment appropriate for ocular surgery.

7. POTENTIAL ADVERSE REACTIONS

Complications associated with EndoArt® implantation include, but are not limited to:

- Excessive corneal thinning
- Corneal melting or perforation
- Anterior or posterior synechiae
- Cornea abrasion, opacity or haze
- Device detachment
- Worsening of corneal edema
- Infection/endophthalmitis
- Inflammation
- Cataract induction
- Increased ocular pressure/glaucoma
- Retinal detachment

8. INSTRUCTIONS FOR USE

Implantation of the EndoArt® is according to clinical discretion and common practice of the physician, and in compliance with the following instructions:

1. Prepare the patient according to standard surgical practice.
2. Position the patient under the surgical microscope.
3. Create a primary entry (e.g.1.2–3.0 mm), with keratome side port and secondary entry point (one or two as necessary) using a stiletto.
4. Optional: Insert an anterior chamber (AC) maintainer with balanced salt solution (BSS) or air.
5. Optional: Create inferior iridotomy
6. Create a descemetorhexis (7-7.5mm(under BSS or air in the AC. **Note:** In case of severe bleeding or uncontrolled vitreous in the AC, consider cancelling EndoArt® implantation.
7. Examine the label on the unopened package of EndoArt® implant for proper specification and expiration date.
8. After opening the cardboard storage container, remove the vial with EndoArt® implant.
9. Inspect the vial carefully for any signs of damage. The device is sterile only if the vial is properly sealed. **Note:** the vial in not sterile
10. Open the EndoArt® vial and carefully remove the implant using sterile, atraumatic instruments.
11. Inspect EndoArt® implant for damage or defects prior to use.
12. Before insertion, ensure the implant is in its right orientation: EndoArt® has a character "(F)" marked on the peripheral surface that should appear correctly (Fig. 1); otherwise, the implant should be overturned.
13. Insert EndoArt® implant into the eye's anterior chamber with forceps or an ocular injector, such as VISCOJECTTM - BIO 2.2 injector produced by Medicel AG.
14. After insertion, ensure again the correct placement and orientation of the implant; otherwise, the implant should be overturned.
15. Position the implant with the air bubble according to center of pupil.
16. Suture primary entrance
17. Fill the AC 80% in volume with air or SF6 gas 20% or C3F8 gas 10% for 20 min. (IOP should be around 25mmHg. If needed, inject BSS/gas to reach the requested IOP, make sure air bubble is no more than 80%).
18. Suture the implant (single suture, nonabsorbable, at exactly 12 O'clock perpendicular to the center, according to Fig. 2). The perpendicular orientation of the suture is important to prevent decentration. The suture will be removed not sooner than 6 weeks from obvious attachment.
19. Massage the cornea gently for enhancing corneal implant attachment, from the suture to 6 o'clock
20. If iridotomy was not performed consider applying pupil dilatation drops, to prevent pupil block.
21. Leave the patient in a supine position for 4 hours after the operation.
22. In case of partial or full device detachment, the re-bubbling procedure may be performed using air, SF6 gas 20% or C3F8 gas 10%, as per the physician's discretion

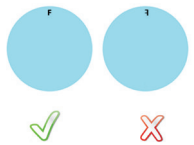

Fig.1 EndoArt® implant orientation

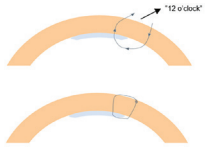

Fig.2 EndoArt® suturing

9 POST OPERATION MEDICAL TREATMENT AND FOLLOW-UP

- Use steroids for at least 6 weeks and antibiotics for at least 2 weeks post operation.
- Post-operative treatment according to standard of care for corneal surgery.

10. INSTRUCTIONS FOR PATIENT

- Instruct the patient to remain with transparent eye shield for 14 days post procedure/re-bubbling
- Instruct the patient not to fly or increase geographical altitude for 3 weeks post air injection. This may lead to increased IOP, pain and pathological damage to the eye.
- Instruct the patient to lay on his back (face up) as much as possible in the first week
- Instruct the patient not doing any heavy lifting or sports activities of any kind for at least 2 weeks after the surgery.
- Instruct the patient not to swim for 4 weeks after surgery
- Instruct the patient to avoid activities that put him/her at risk for infection (like gardening, cleaning out stalls, attics, etc.) for the first month after surgery.

11. POTENTIAL COMPLICATIONS AND PROPOSED SOLUTIONS

Phenomenon	Implant Position	Offered Solution
Corneal edema	Implant is fully detached	Re-bubbling/new implantation
	Implant is partially detached	Re-bubbling procedure
Corneal thinning, risk of perforation	Implant is attached	Periodical physician's monitoring: In case of corneal thinning to <90% of its normal thickness, close follow-up should be performed. When the cornea thins to <80% (e.g. CCT around 400µm) of its normal thickness, consider removing the implant.
Perforation	Implant is attached	Surgical correction
Implant migration	Not centered	Implant re-attachment/re-bubbling/new implantation
Eye infection	NA	Treat as per standard of care
High intraocular pressure	NA	Treat as per standard of care
Epithelial bullae	Implant is attached	Follow up
	Implant is partially detached	Re-bubbling
Iris adhesions and elevated IOP	NA	Provide standard glaucoma treatment or adhesion treatment surgery
Haze	NA	Consider implant removal DSAEK/DMEK procedure

12. STERILIZATION AND STORAGE

The device is sterilized by moist heat.
The device is non-pyrogenic.
To provide maximum protection, store the device in its original, unopened package at room temperature (up to 55°C). Avoid excessive heat or cold.
The implant must be used before the expiration date printed on the package label.

13. DISCLAIMER OF WARRANTY

Note: EndoArt® referred to as "the product," has been manufactured under carefully controlled conditions. EyeYon Medical has no control over product use and usage conditions. EyeYon Medical disclaims all warranties and representations, both expressed and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. EyeYon Medical shall not be liable to any person or entity to any, incidental or consequential damages, including, without limitation, for any medical expenses in connection to the product, caused by any use, defect, correspondence with description, non-infringement and/or any malfunction of the product, whether a claim for such damages is based upon representation, warranty, contract, tort, operation of law, statutory and/or otherwise. No person has any authority to bind EyeYon Medical to any representation or warranty with respect to the product.

The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected.

14. LABEL GRAPHICAL SYMBOLS DEFINITION


Use by


Lot number


Do not reuse


Do not resterilize


Catalog number


Consult instructions for use


Do not use if package is damaged


Method of sterilization using moist heat


Keep dry


Keep away from sunlight


Upper limit of temperature


Manufacturer


Non-pyrogenic

15. REPORTING OF ADVERSE REACTIONS

All serious adverse events and adverse reactions relating to EndoArt® implant should be reported to EyeYon Medical Ltd.

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