



# New Approach for Corneal Healing

Nahum Ferera, CEO & Co-Founder



# Executive Summary, EndoArt®

## A TOTAL OF +200 IMPLANTATIONS, Beyond 5 Years OF Follow-up

EndoArt® was found to be safe with no device-related SAE Phase II interim results:

**Vision – 58% 6 months post-op improved in 2 lines\* or more**

**Eye Pain\*\* – 77% of the patients improved from baseline by more than 20 points**



EndoArt is under Breakthrough designation  
Agreement on IDE submission for single arm pivotal Study (planned July 2023)



EndoArt is CE approved, 1<sup>st</sup> paid (and reimbursed EndoArt shipped, June 2023)



EndoArt is under Innovation Path (Green Channel)  
Agreement with NMPA on the initiation of Pivotal trial.



Approval to commercialize in Hainan.



# The Solution: EndoArt®

- Optically clear
- Flexible
- Biocompatible



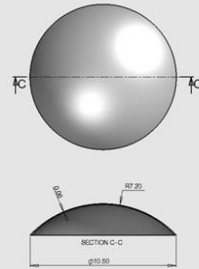
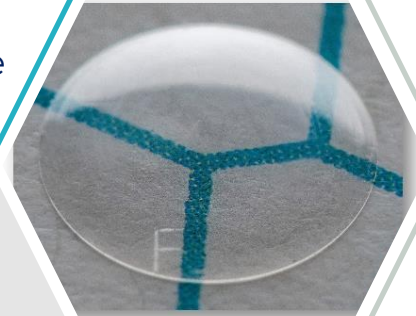
Ready to use



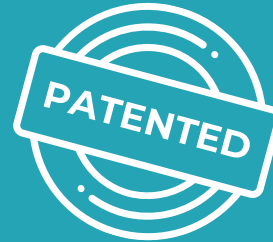
Treats only root cause of corneal edema



Leaves cornea intact



- Synthetic
- Inert material
- Dome Shaped

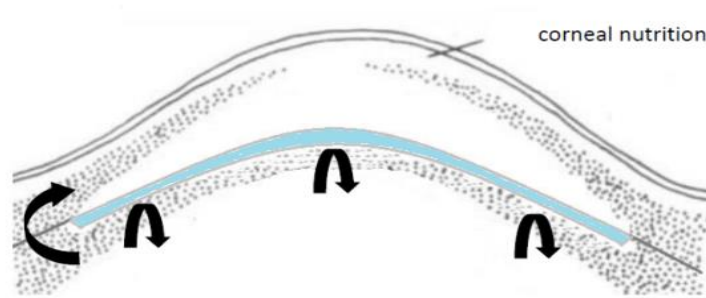


CE Approved

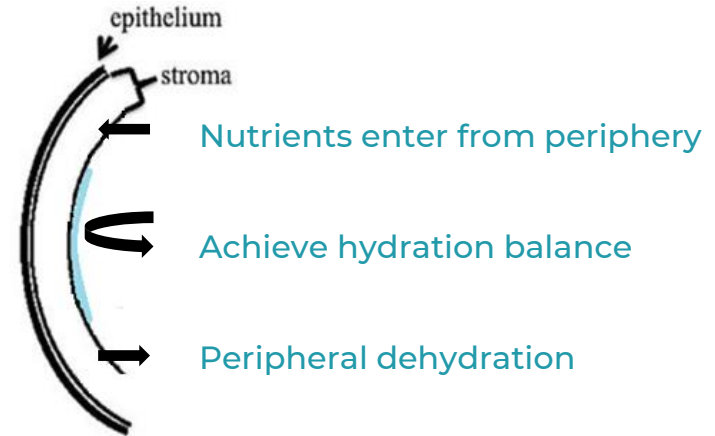
Accelerated regulatory paths in USA, China

# Mechanism of Action

- ✓ Impermeable barrier to fluid
- ✓ Decrease passive movement of aqueous humor into corneal stroma
- ✓ Restores fluid homeostatic balance in stroma



Prevents aqueous humor from entering the cornea



**Result: Decrease of corneal edema. More than 3 years of human safety & efficacy**

# Global Use Model

## FAILURE AFTER FIRST GRAFT

- Failure rates after 1<sup>st</sup> failed cornea transplant: **26.7%** after 12 month, **42.3%** after 4 years<sup>1</sup>
- EK in eyes with AC IOL: **25%** in 3 years, **39%** in 5 years<sup>3</sup>
- EK in eyes with neovascularization: **30%** in 3 years, **64%** in 9 years<sup>4</sup>
- **Regrafting is the third most common indication in the US**, and the fastest growing
- Potential regrant patients are not currently considered for a repeat regrant

## PATIENT SUITABILITY - GLAUCOMA SURGERY

- Failure post Glaucoma surgery: **25%** at 12 months, **73%** at 4 years<sup>2</sup>
- How common is Glaucoma surgery? 325,000<sup>5</sup>, 40% CAGR in the US (significant growth in the US and EU)
- 100 patients who need transplant today, all receive human tissue with low expectations of success

## PATIENT PREFERENCE

Given the choice, patients would prefer synthetic over human tissue, patients would also like to have less waiting time prior to surgery<sup>7</sup>

## OFF THE SHELF

How common is damaged/inadequate human tissue at time of surgery<sup>6,7</sup>

**LACK OF TISSUE** (ROW developing markets): 1 human tissue for every 70 patients<sup>8</sup>



1. Zafar S, et al. Postoperative complications in medicare beneficiaries following endothelial keratoplasty surgery. Am J Ophthalmol 2020;219:1-11.

2. Sorokin N, Mimouni M, Ksilevsky E, Boutin T, Cohen E, Trinh T, Santilli G, Stomovoi AR, Chan CC, Rootman DS. Four-Year Survival of Descemet Membrane Endothelial Keratoplasty in Patients With Previous Glaucoma Surgery. Am J Ophthalmol. 2020 Oct;218:7-16. doi: 10.1016/j.ajo.2020.05.020. Epub 2020 May 22. PMID: 32446739

3. Mehta, J. S. et al. Endothelial Keratoplasty with anterior chamber intraocular lens versus secondary posterior chamber intraocular lens. doi:10.1136/bjophthalmol-2020

4. THE AUSTRALIAN CORNEAL GRAFT REGISTRY 2015 REPORT KA Williams, MC Keane, RA Galettis, VJ Jones, RAD Mills and DJ Coster Department of Ophthalmology, Flinders University South

5. <https://www.ophtalmologyglaucoma.org/article/52589-4196/21100085-57/fulltext>

6. KOL Interviews

7. Market Research

8. Gains, Global Survey of Cornea Implantation and Eye Banking, JAMA Ophthalmology, 2016;134(2):167-173.

# Value Proposition

## Donor Tissue

<b>Availability</b>	Limited, geographically dependent
<b>Cost</b>	2,000 – 2,500 euro for pre-cut cornea Financial burden on healthcare systems (eye banks, special storage and handling conditions)
<b>Ease of use</b>	Human tissue is difficult to handle
<b>Physician</b>	Specialized cornea surgeons, ~ 450 in the EU
<b>Learning Curve</b>	Very long, up to 2 years, at least 70 surgeries
<b>Procedure time</b>	Lengthy, human tissue is challenging to work with
<b>Shelf life of Material</b>	Human donor tissue, 2 weeks Shelf Life, long term durability unknown
<b>Side effects</b>	Failed Graft: up to 15% (first surgery), 30% after first failed Graft (2 <sup>nd</sup> attempt)
<b>Post Treatment</b>	Can reach to Lifetime (steroids, rejection medicine)

## EndoArt®

Long shelf life, immediately available
Low manufacturing costs, commercially priced below human tissue
Simple, resilient, minimal invasive
Any anterior segment surgeon (>100K)
Short learning curve for Cornea Surgeon, 3-4 procedures
Very short, up to 10 minutes
Artificial polymer, permanent implant, SL of years
No rejection, no possible infection
6 weeks