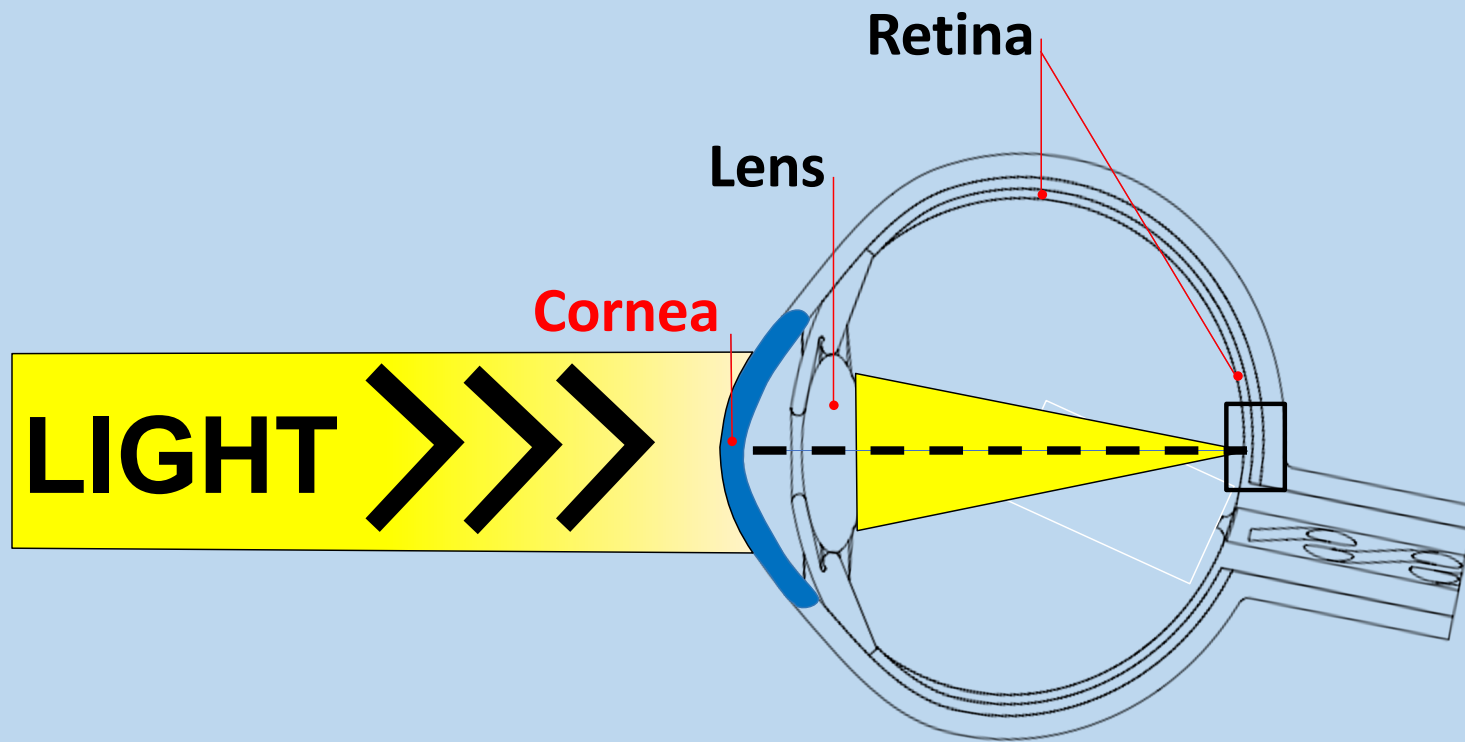




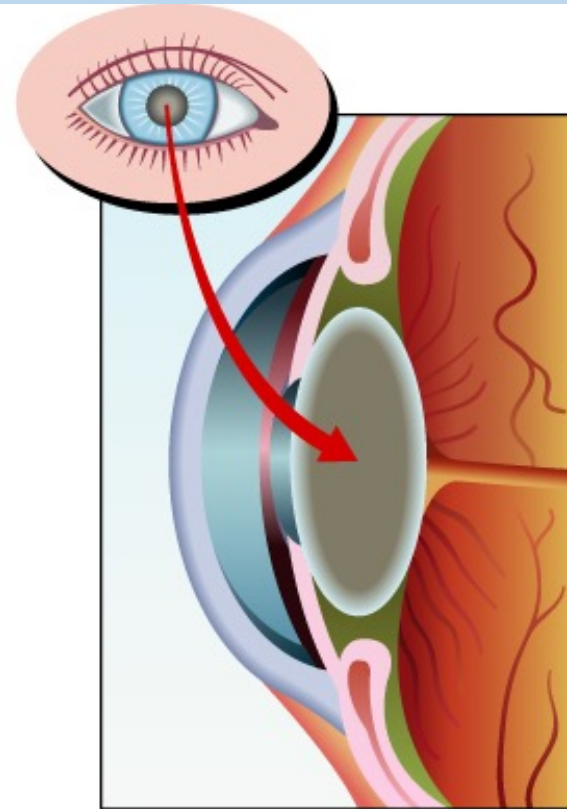
**THE FUTURE OF VISION**

**THE PROJECT IN DETAIL**

# VISUAL PERCEPTION



# CATARACT



CATARACT

## **KEY FIGURES**

**$\pm 100,000,000$**

**PEOPLE HAVE CATARACT**



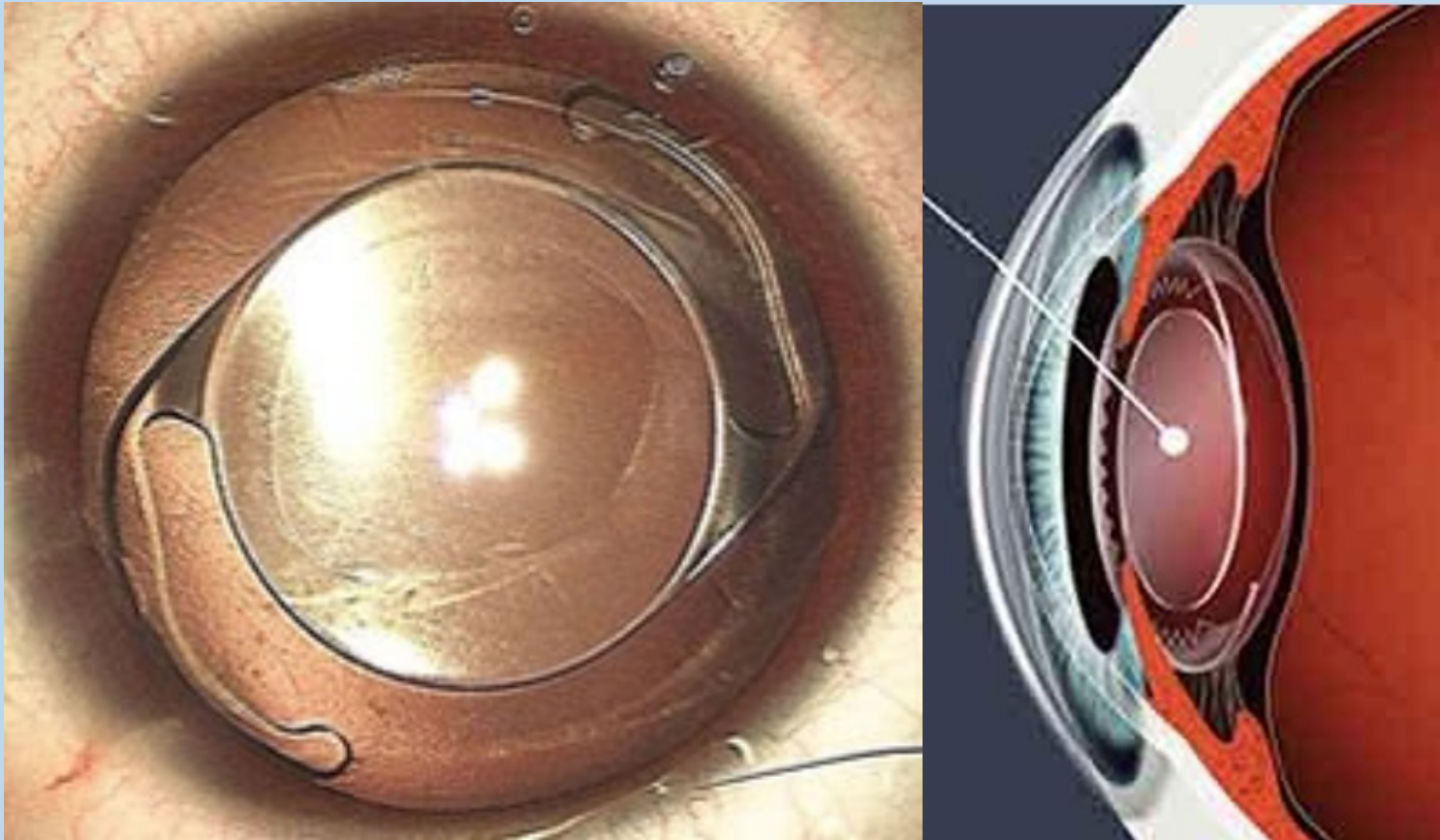
# KEY FIGURES

**±10,000,000**

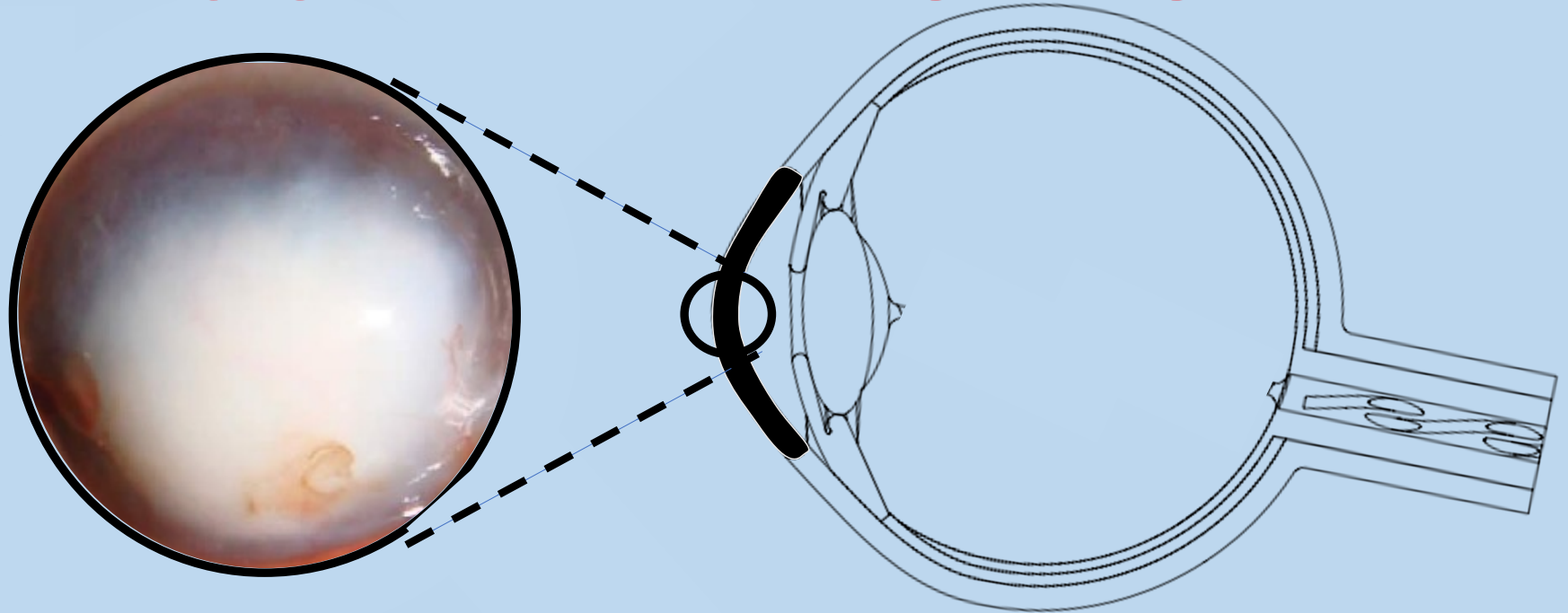
**CATARACT SURGERIES**

**PERFORMED EACH YEAR**

# ARTIFICIAL LENS



# CORNEAL DISEASE



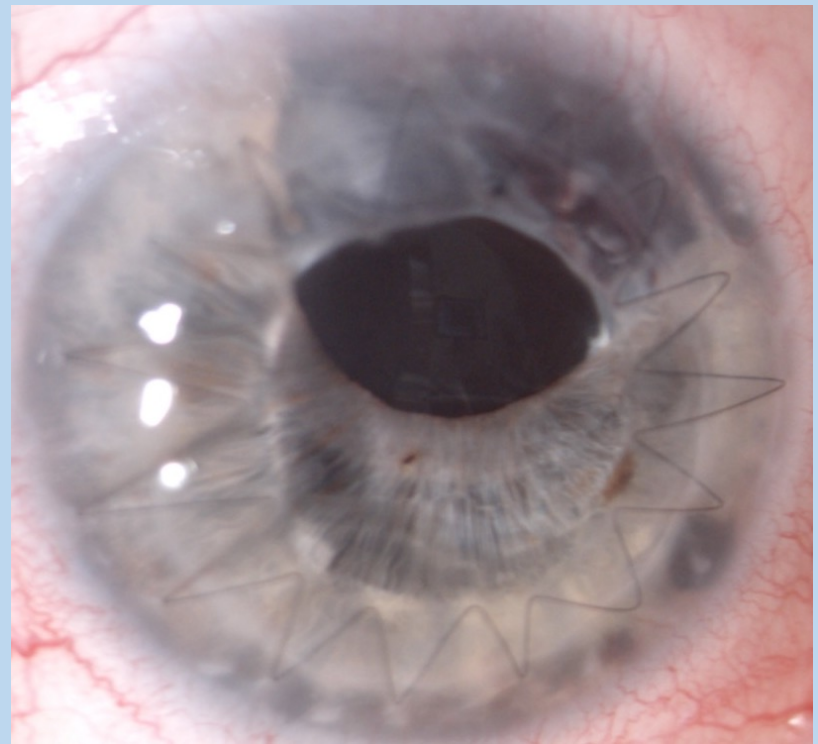
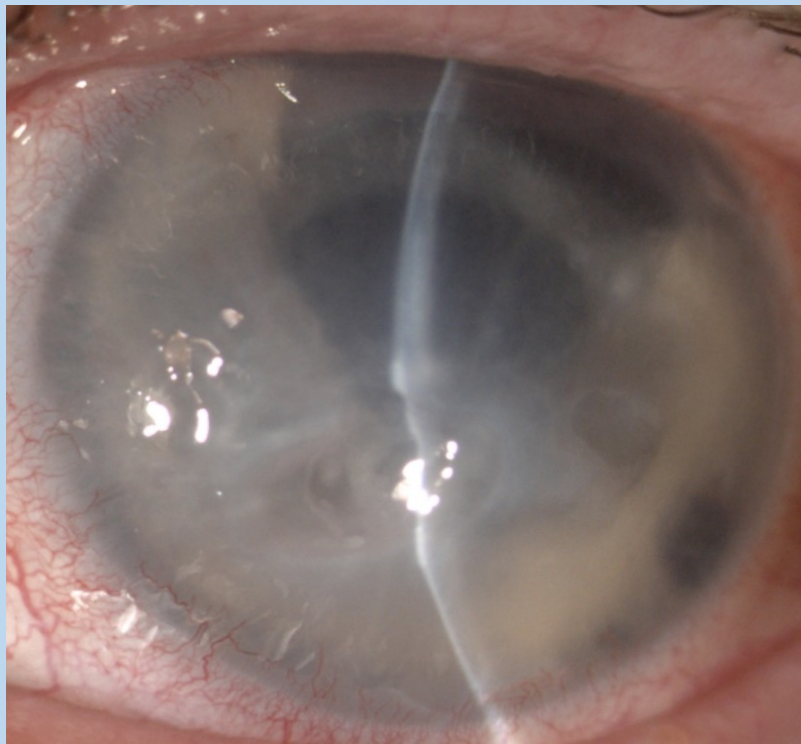
**IS ONE OF THE LEADING CAUSES OF  
BLINDNESS**

## KEY FIGURES

**±10,000,000**

**SUFFER FROM CORNEAL  
BLINDNESS IN BOTH EYES**

# CORNEAL TRANSPLANT



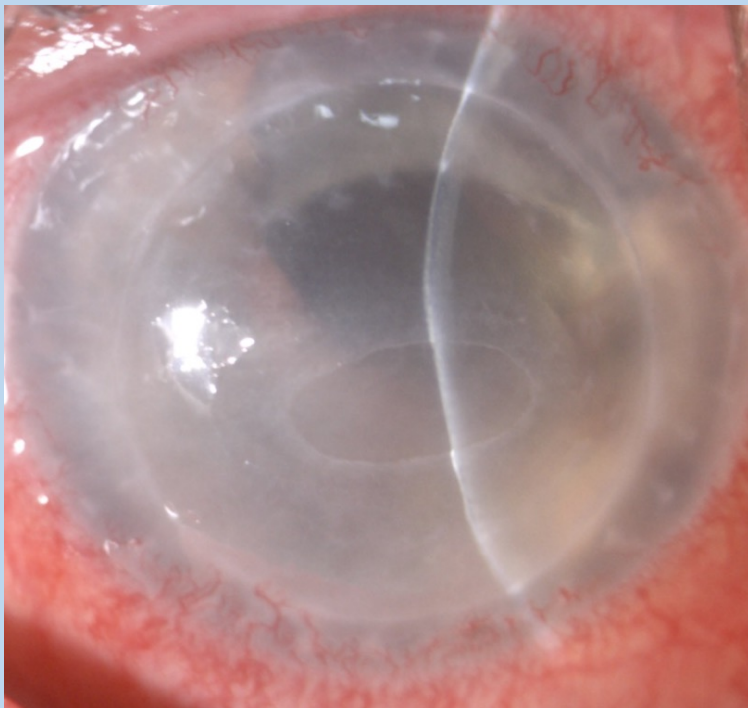
## **KEY FIGURES**

**ONLY 185,000  
CORNEA TRANSPLANTS  
PER YEAR**

# **REASONS FOR THIS** **DISCREPANCY**

- **DONOR TISSUE SHORTAGE**
- **LACK OF GLOBAL ACCESS**
- **NEED FOR LONG-TERM CARE**

# **Failed Corneal Transplant = #2 Indication for Transplantation**



## **MAIN CAUSES:**

**Immune Rejection**

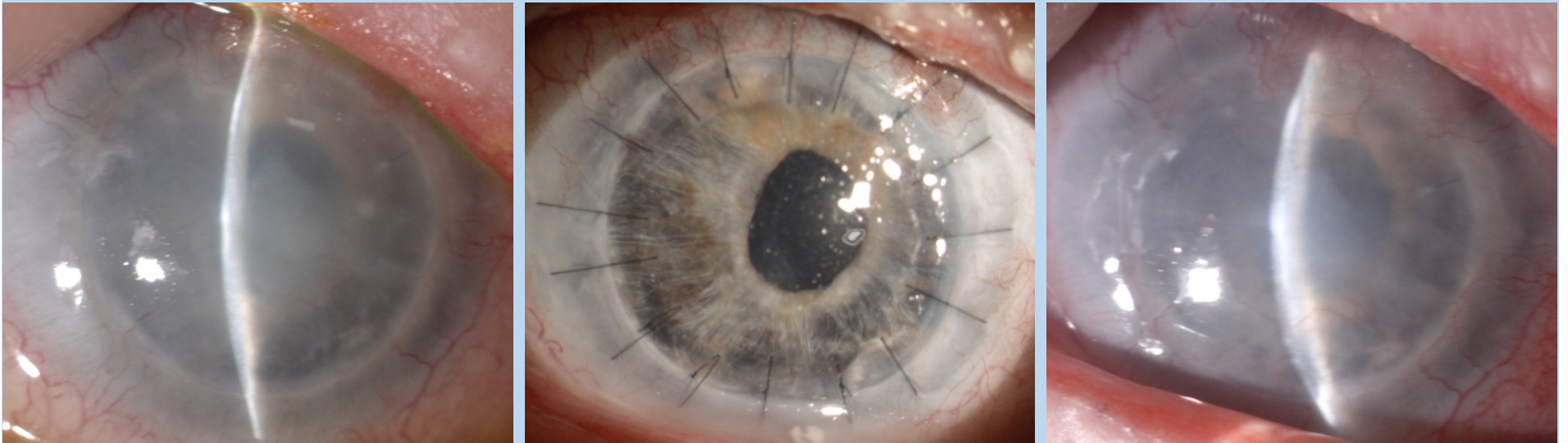
**Distorted Vision**

**Endothelial Decay**

**Infections, Others...**



# A Corneal Transplant Can Be



**DOOMED TO FAIL !!!**

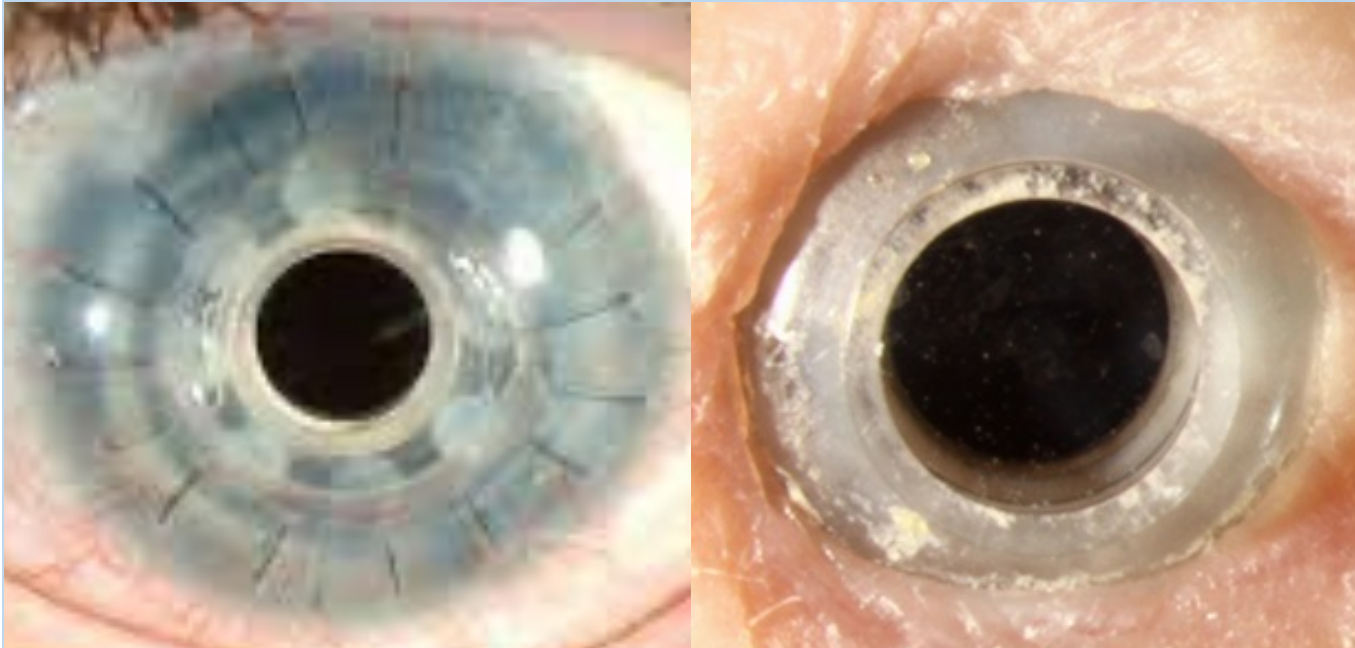
**At Least 7000-8000**  
**Corneal Transplants**  
**Every Year Are**  
**DOOMED TO FAIL !!!**

**MANY MORE ARE  
CONSIDERED  
INELIGIBLE FOR  
TRANSPLANTATION**

**!!!**

# **ARTIFICIAL CORNEA**

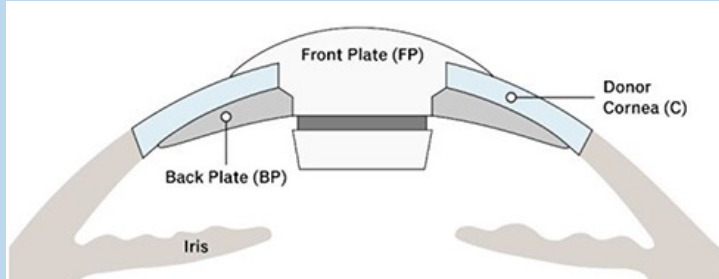
## ***BOSTON KERATOPROSTHESIS***



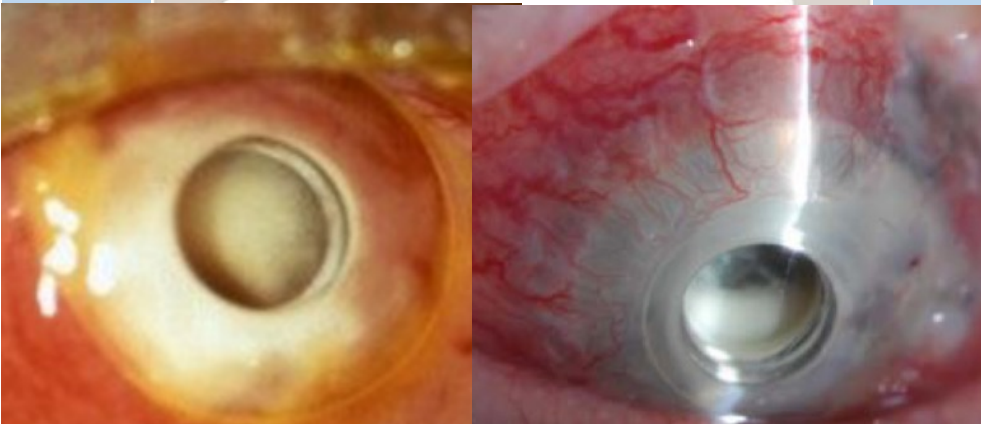
**CURRENT  
STATE  
OF  
THE  
ART**

# ARTIFICIAL CORNEA

**TRANSCORNEAL = Basic Problem!!!**



**COMMUNICATION  
BETWEEN INSIDE  
AND OUTSIDE OF  
THE EYE!**



**EXTRAOCULAR and INTRAOCULAR!**

# ARTIFICIAL CORNEA ???

*Restoring Sight ???*

Up to 60% of Patients Remain

**LEGALLY BLIND**

With Snellen Vision  $< 1/10 = 20/200$

# KEY FIGURES

Use of Donated Tissue	2019	2020	2021	2022	2023
Corneal Grafts Total	85,601	66,278	79,641	79,126	86,986
Penetrating Keratoplasty	35,919	25,023	30,412	28,728	31,001
Anterior Lamellar Keratoplasty	2,146	1,072	1,307	1,230	1,398
Endothelial Keratoplasty	35,555	29,947	35,532	36,173	39,883
Keratolimbal Allograft	110	119	134	122	109
Keratoprosthesis (K-Pro)	267	174	175	136	156
Glaucoma Shunt Patch or other non-keratoplasty use	1,018	873	839	920	1,082
Other keratoplasty (experimental surgery)	44	11	25	31	27
Unknown or Unspecified	4,679	2,777	3,614	4,495	4,456
Sclera	5,999	3,151	5,614	2,247	2,195
Long-Term Preserved Corneas	8,614	9,093	12,626	4,580	5,362
Keratoplasty	126	125	82	134	306
Glaucoma Shunt Patching	8,420	7,037	10,283	4,444	5,045
Other Surgical Uses	68	1,931	2,261	2	11
Research	13,743	11,336	14,222	13,943	13,983
Training	9,487	6,504	7,425	6,614	8,239

# ARTIFICIAL CORNEA

BOSTON K-PRO





# ARTIFICIAL CORNEA ???

*Restoring Sight*



**Keraklear**  
PMMA + PEG

**Korea Seoul-Type**  
PMMA + PEG

**Alphacor**  
PHEMA

**Corneat**  
Synthetic Material

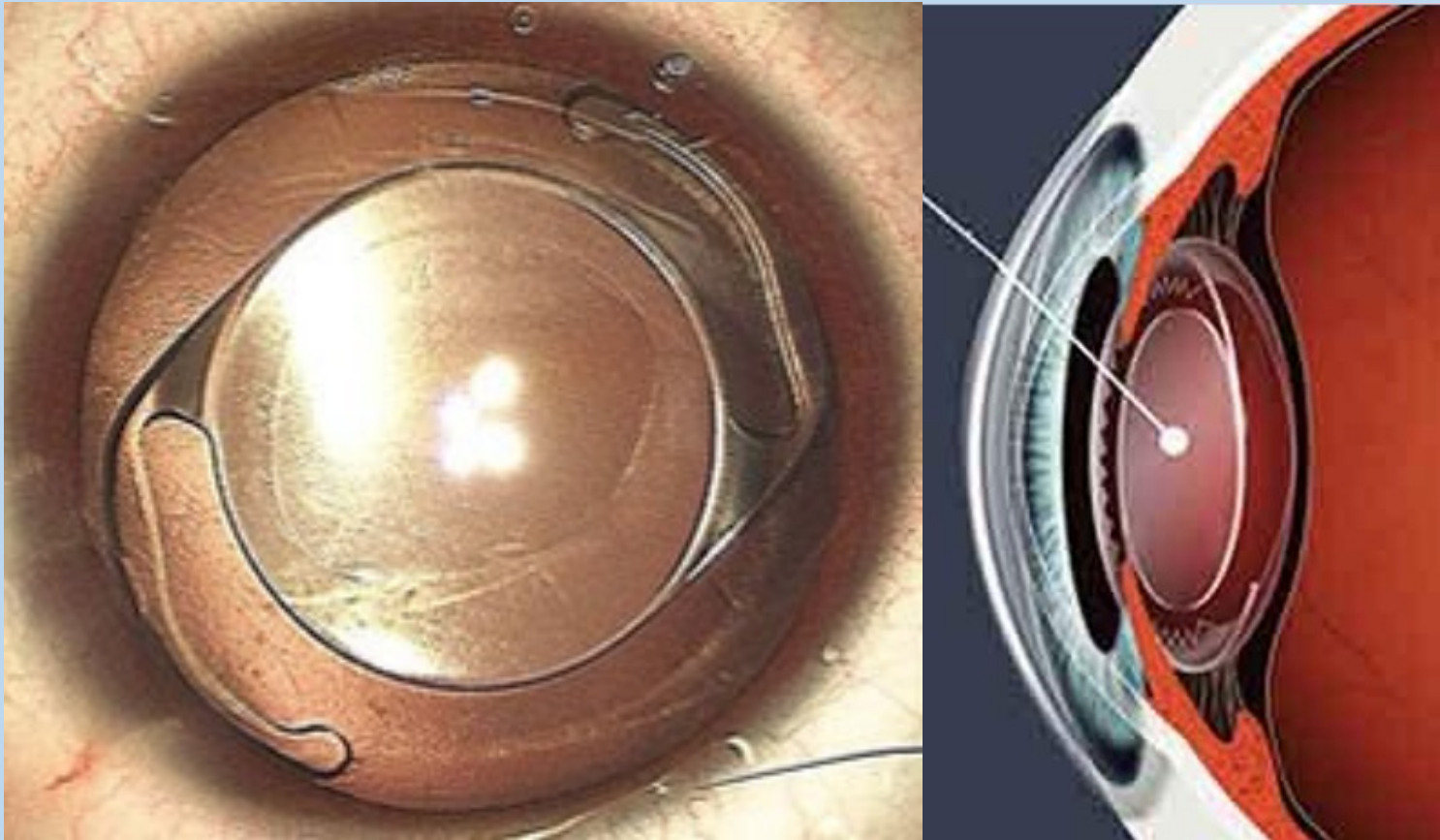
# **BIOCOMPATIBILITY**

**A PROBLEM OF TYPE OF  
MATERIAL**

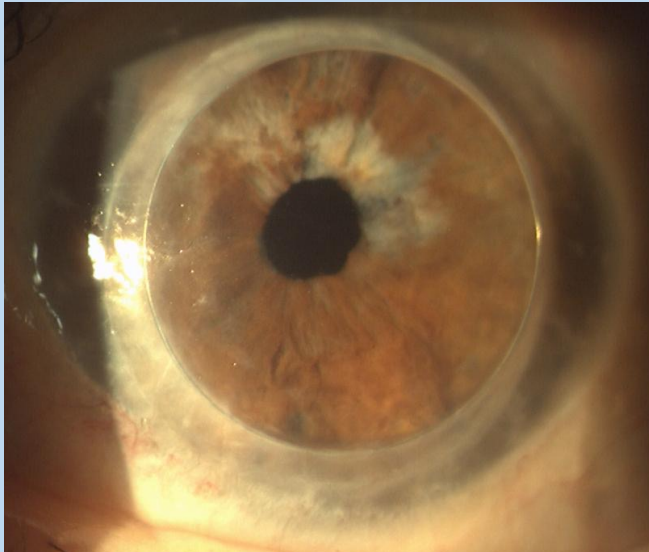
**VS**

**SITE OF IMPLANTATION**

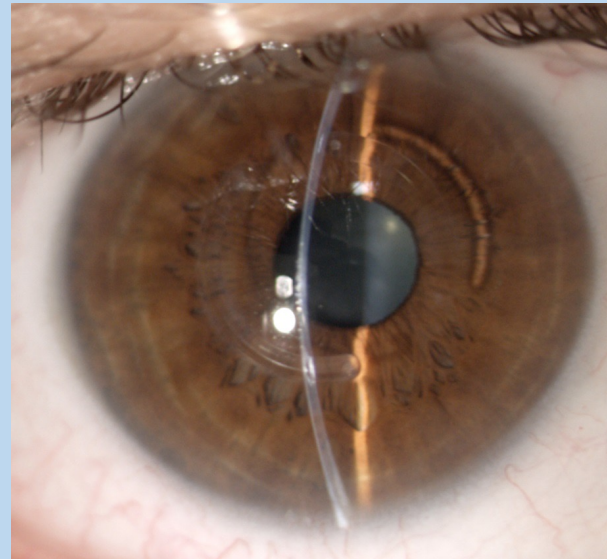
# ARTIFICIAL LENS



# **SOLUTION: BIOCOMPATIBLE INTRACORNEAL IMPLANTS**

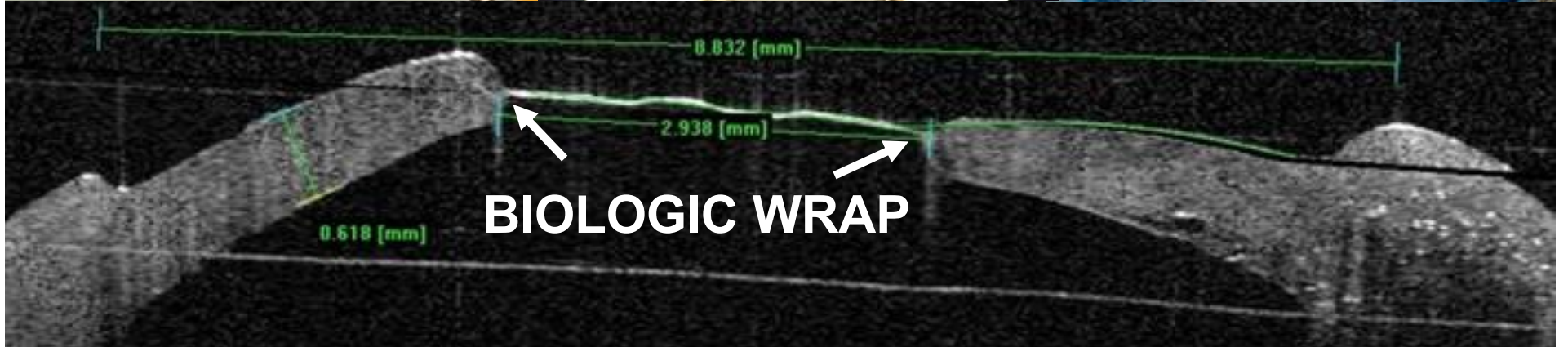
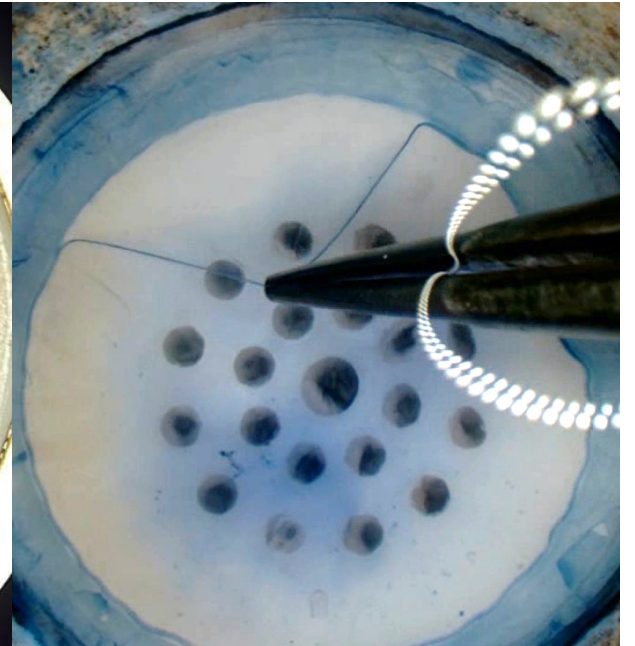
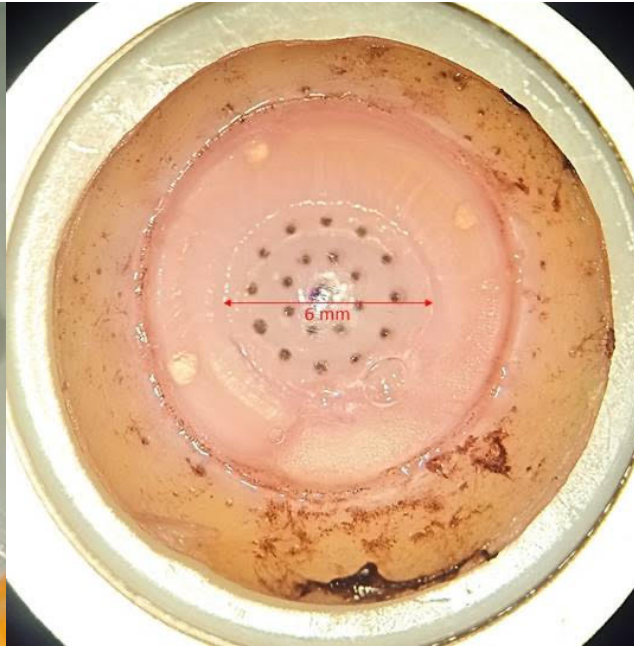
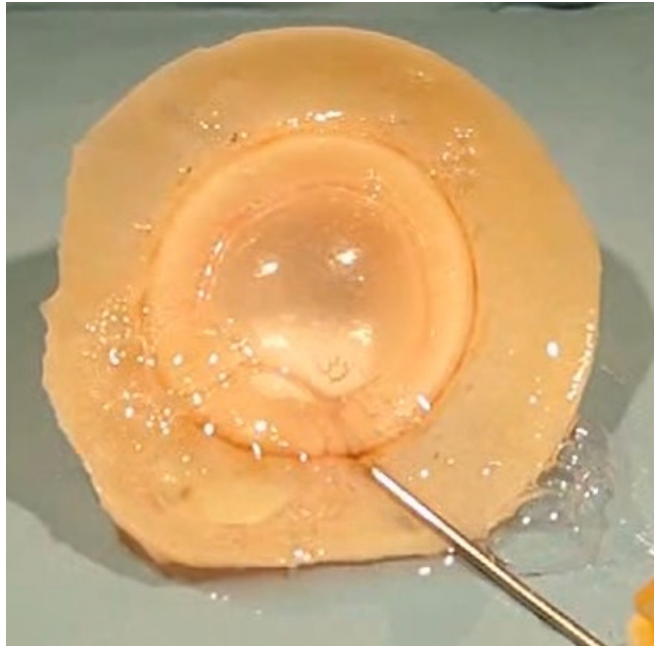


**15Y Postop Intracorneal Titanium  
Ring**

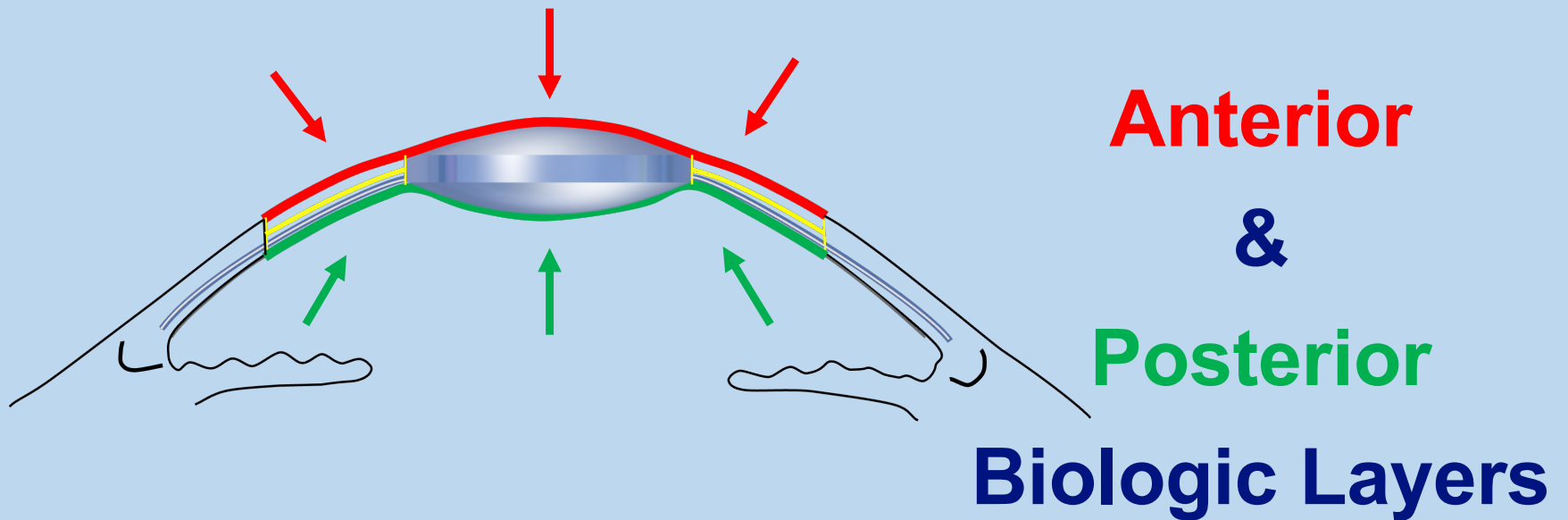


**10Y Postop Intracorneal PMMA  
Ring Segment**





# INTRA-KER



# PATENT

- **Priority Date:**  
**Sep 2021**
- **Filing Date:**  
**Sep 2022**

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau

(43) International Publication Date  
23 March 2023 (23.03.2023)



(10) International Publication Number  
**WO 2023/041747 A1**

(51) International Patent Classification:  
*A61F 2/14* (2006.01)

(21) International Application Number:  
PCT/EP2022/075851

(22) International Filing Date:  
16 September 2022 (16.09.2022)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
63/245,384 17 September 2021 (17.09.2021) US  
63/351,480 13 June 2022 (13.06.2022) US

(72) Inventor; and

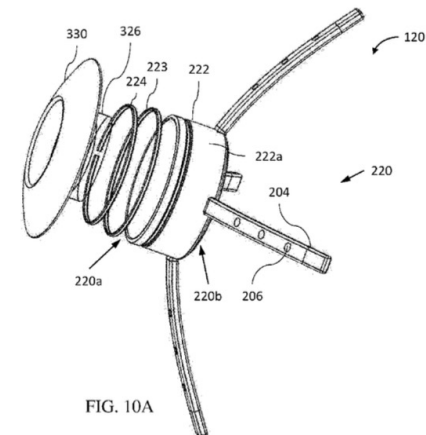
(71) Applicant: **BUSIN, Massimo** [IT/IT]; Via Sisa 33, 47122  
Forlì (IT).

(72) Inventors: **ELIACHAR, Eliahu**; 25 Yefe Nof St.,  
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**LILACH, Nir**; 3658200 Kfar Yehoshua (IL). **LAVAN,**  
**Ron Michael**; 16 Hatamar Street, 3432520 Haifa (IL).

(74) Agent: **BOULT WADE TENNANT LLP**; Salisbury  
Square House, 8 Salisbury Square, London, Greater London  
EC4Y 8AP (GB).

(81) Designated States (*unless otherwise indicated, for every  
kind of national protection available*): AE, AG, AL, AM,  
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,  
CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM,  
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,  
HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE,  
KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU,  
LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA,  
NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO,

(54) Title: INTRACORNEAL OPTICAL IMPLANT



# **OFF-LABEL USE**

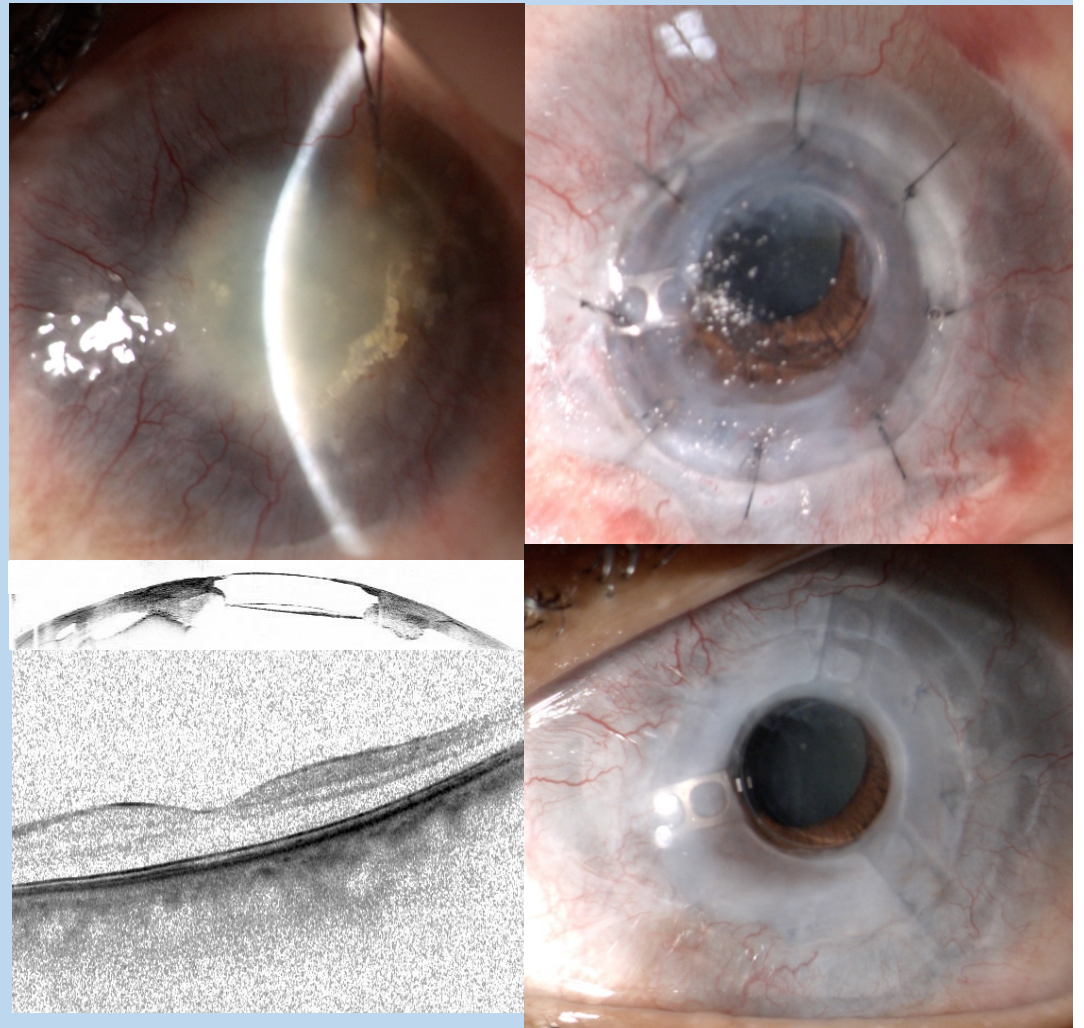
- 1. No Intracorneal Device Available for Same Indication with CE Marking**
- 2. Custom-made in Accordance with Specifications of the Surgeon**
- 3. For Clinical Investigation in a Patient under Direct Responsibility of Surgeon and Manufacturer**

EU Medical Device Regulation 2020/561

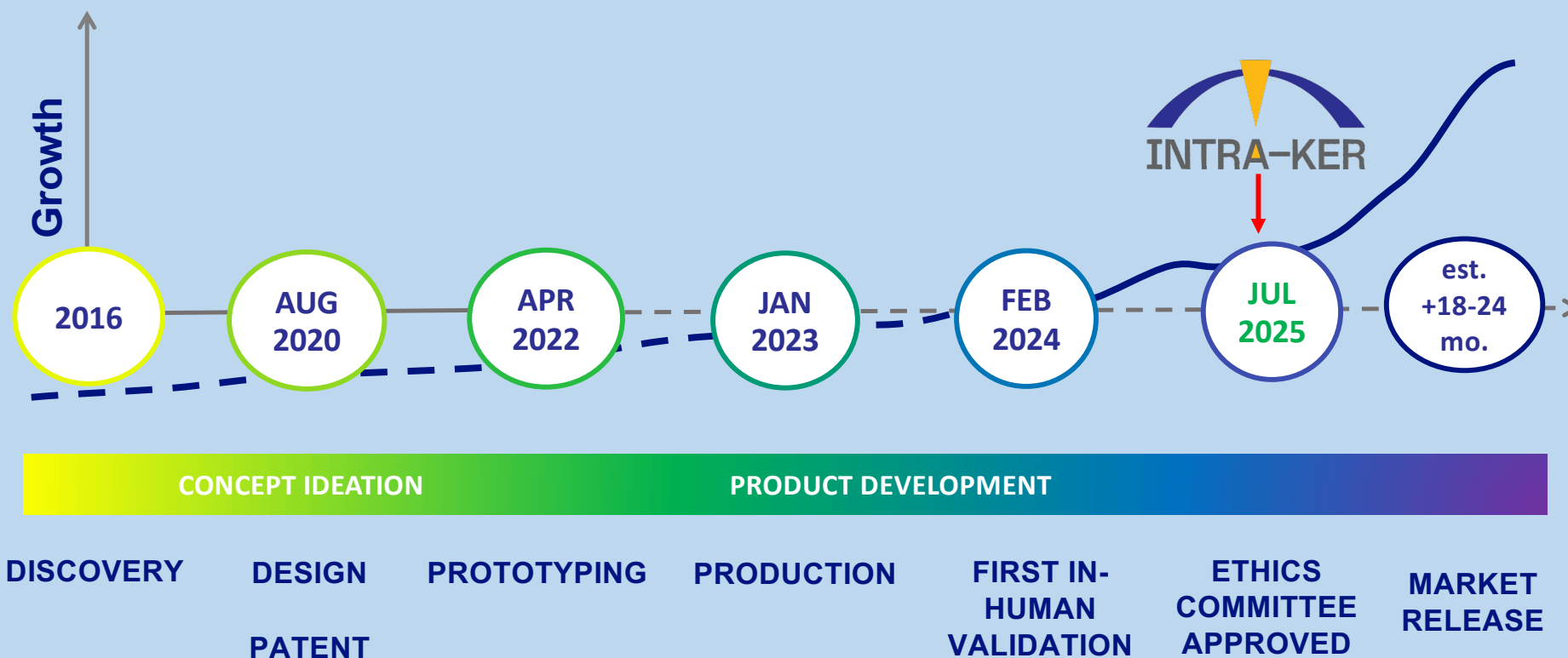


**43 year old ♀**

- **Preop VA: LP**
- **Chemical Injury**
- **Phakic**
- **s/p PK (2x)**
- **12 mos VA: 20/50**



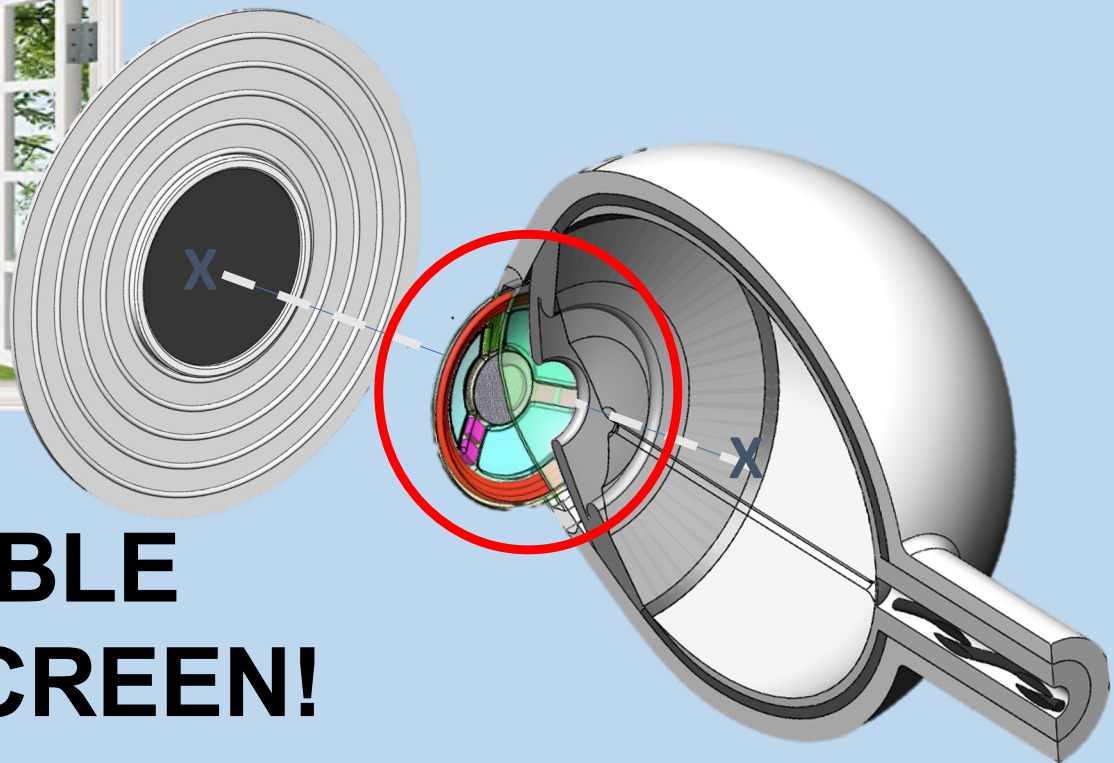
# OUR STRATEGIC TIMELINE



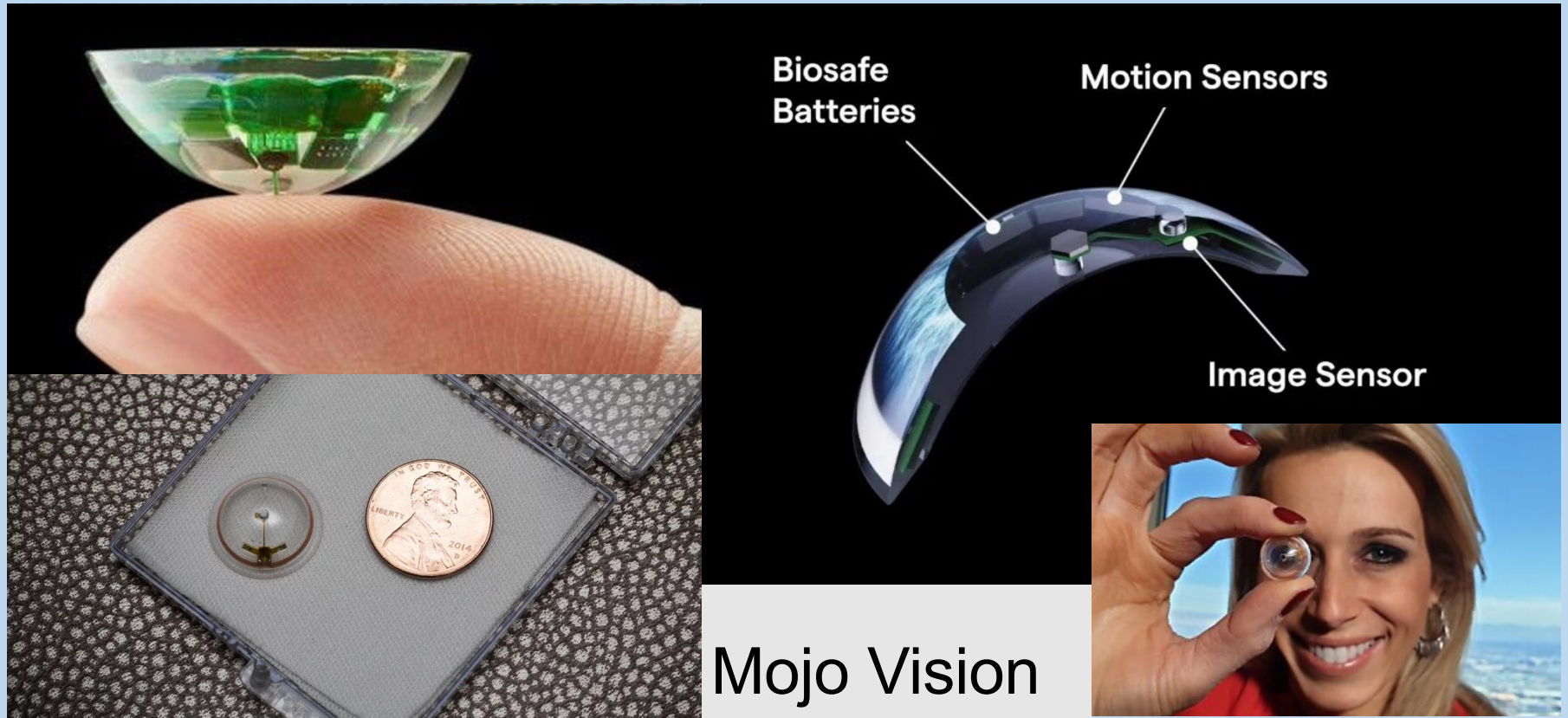
# OUR VISION !!!



## IMPLANTABLE MICROLED SCREEN!



# SMART CONTACT LENS





# SMART GLASSES FOR BLINDNESS???

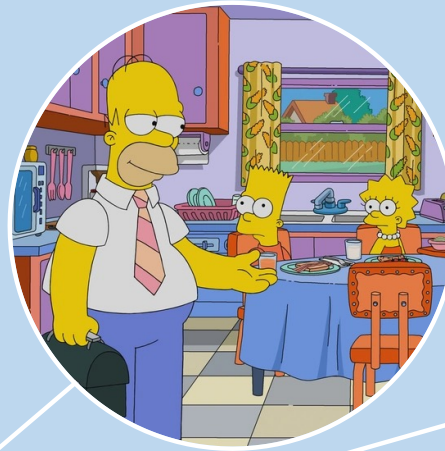
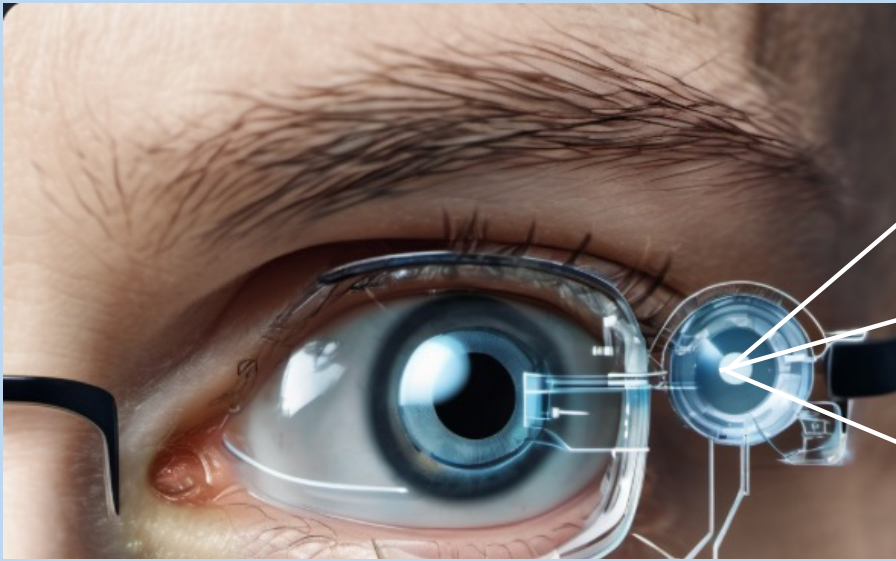


**PROJECT ARIA  
(FACEBOOK/ESSILUX)**



**GOOGLE GLASS**

# OUR VISION !!!



# INNOVATION PATHWAY

INTRACORNEAL  
MICROLED SCREEN\*

INTRACORNEAL  
OPTICAL DEVICE\*



- Product Launch
- Production
- **Clinical Trial**
- ✓ Validation
- ✓ Prototyping
- ✓ Planning and Design

\* PROTECTED IP

# SCIENTIFIC CONSORTIUM for Horizon Pathfinder



**Prof. Massimo Busin**



**Prof. Luigi Rovati**



**Prof. Heidi Ottevaere**



**Prof. Mario Giardini**



**Università  
degli Studi  
di Ferrara**



**UNIMORE**  
UNIVERSITÀ DEGLI STUDI DI  
MODENA E REGGIO EMILIA



**VRIJE  
UNIVERSITEIT  
BRUSSEL**



**University  
of Dundee**



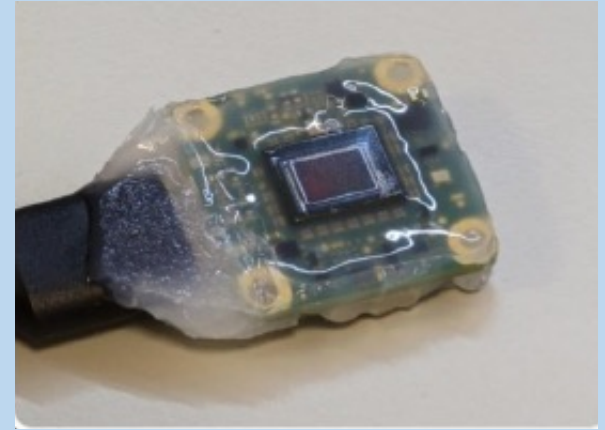
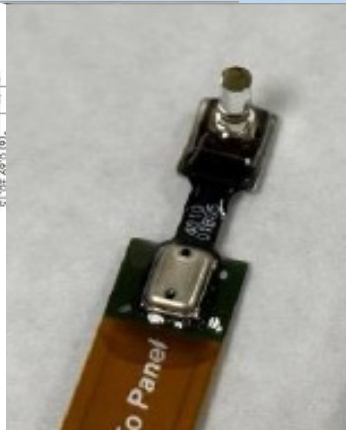
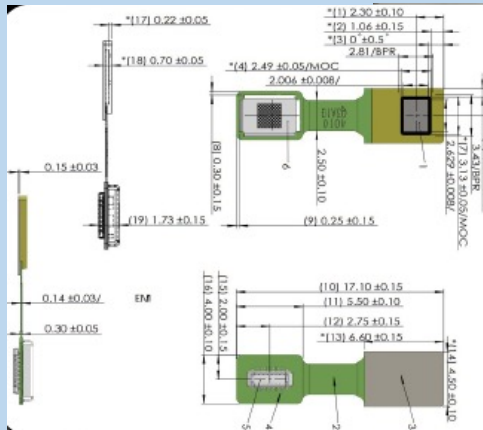


## **Key Accomplishments**

- ✓ **Prototype Fabrication**
- ✓ **Waterproofing & Encapsulation**
- ✓ **Preliminary Optical Testing**
- ✓ **Ex Vivo Human Eye Testing**
- ✓ **Proof of Concept**

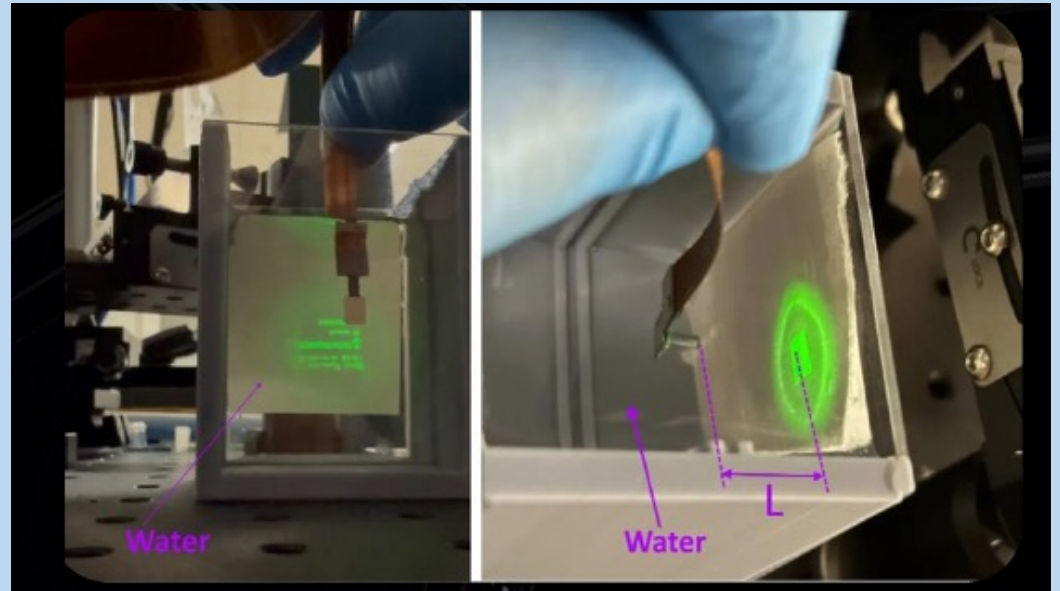
# PROTOTYPE

## Micro-LED Screen + Focusing Lens Image Sensor



# PRELIMINARY TESTING

- Optical Testing
  - Image Generation
- Waterproof Validation

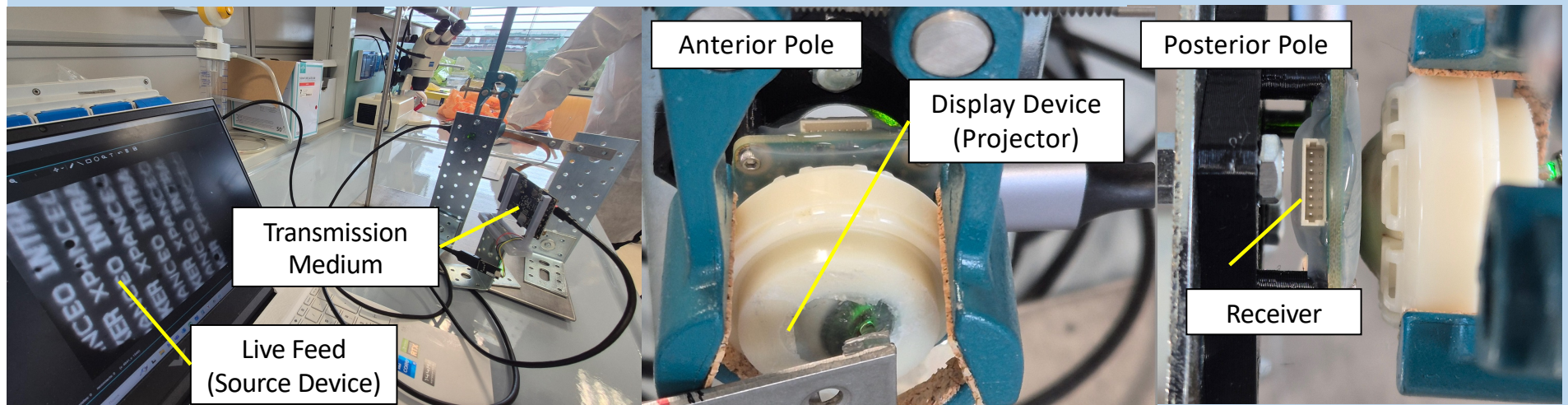


# EX VIVO EXPERIMENT

Image Transmission Set-up Connected  
to Display Projection System

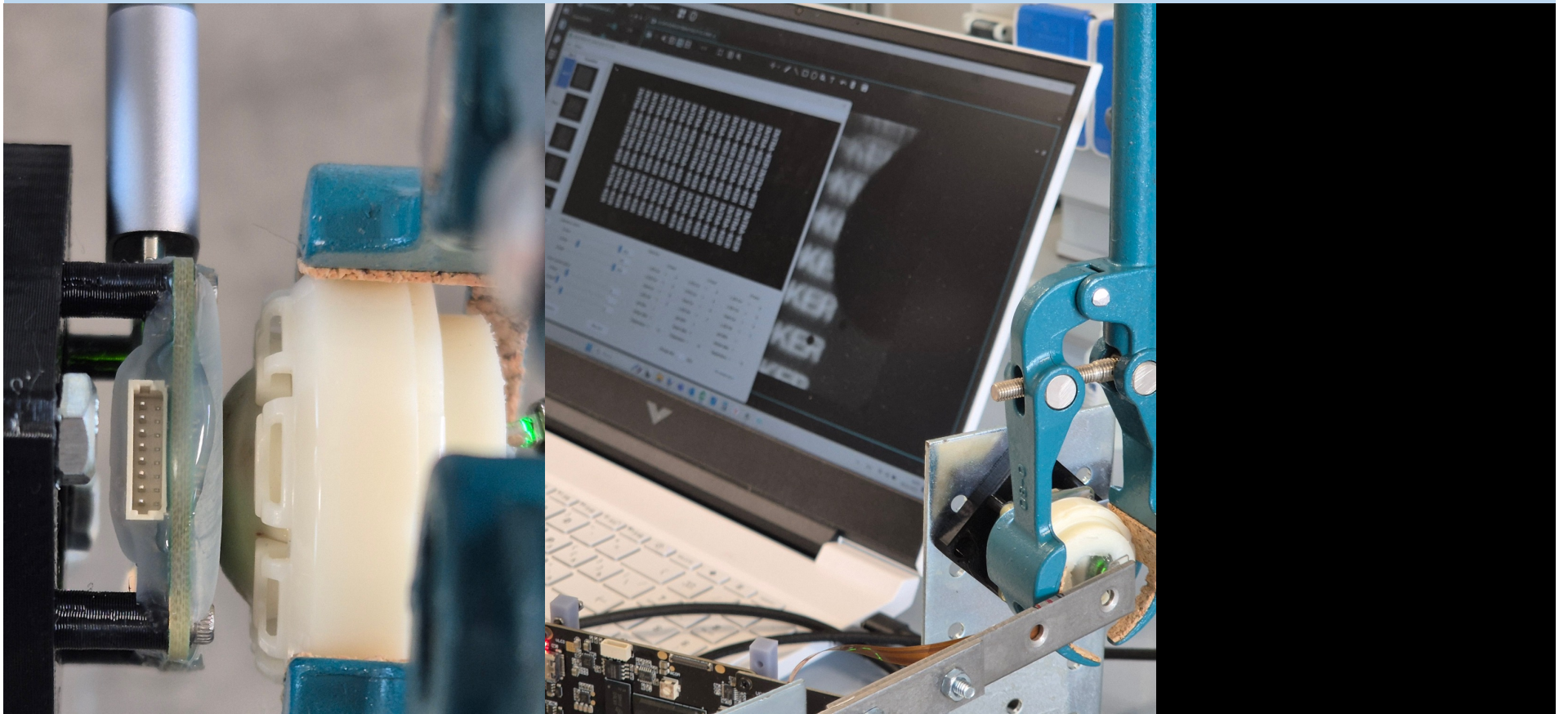
Display Projection System  
Applanated onto INTRA-KER  
Biologic Scaffold

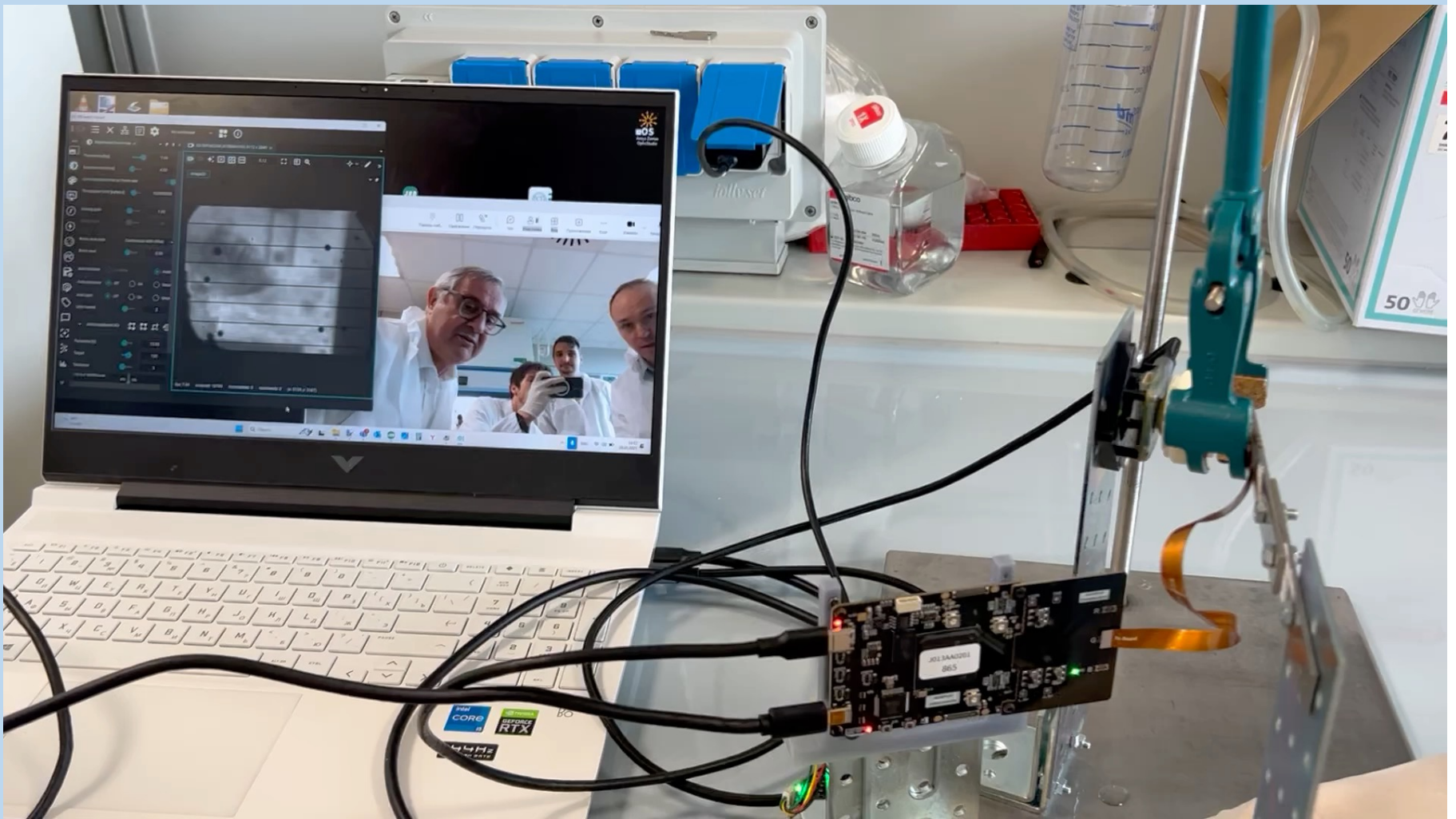
Receiver Camera Set-up





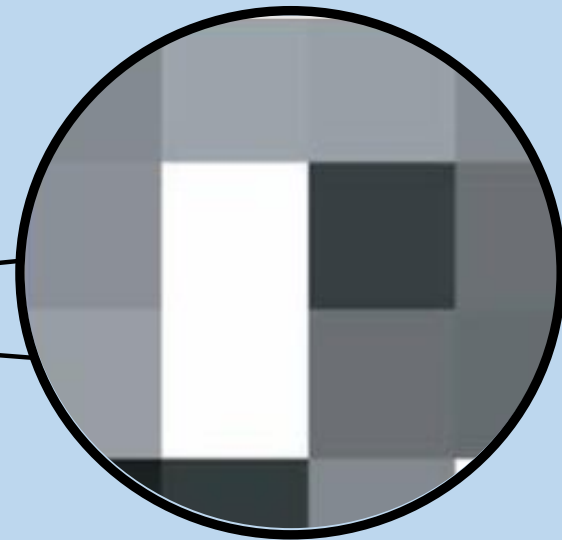
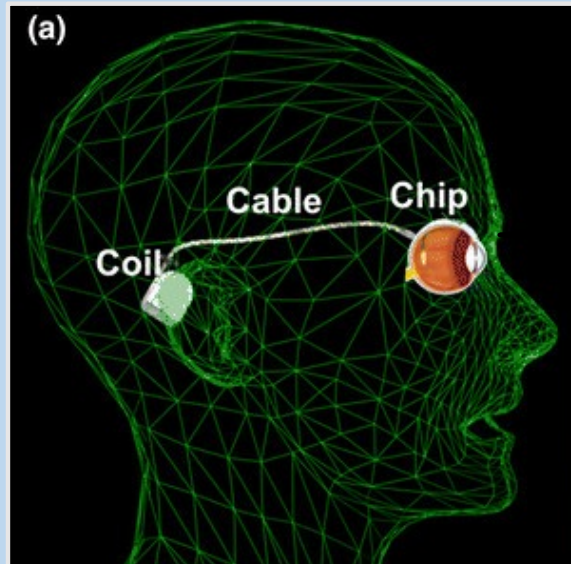
# FUNCTIONAL TESTING





# ARTIFICIAL RETINA

ELECTRICAL NERVE STIMULATION OF RETINAL CELLS



Grating Visual Acuity :  
 $1.8^{\circ} \sim 20/1262$

Limited to PATTERN Vision!



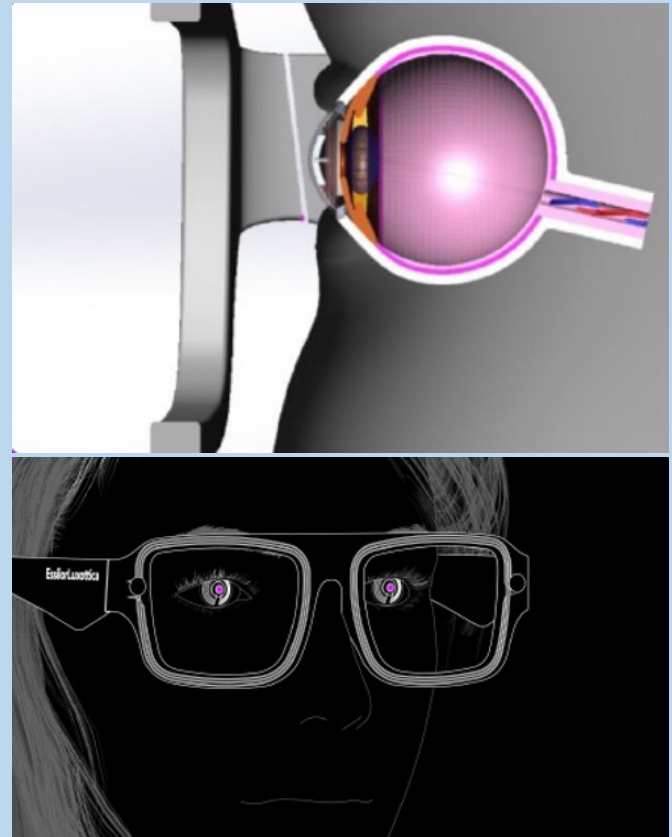
# ARTIFICIAL RETINA



**±\$150,000 PER  
DEVICE**

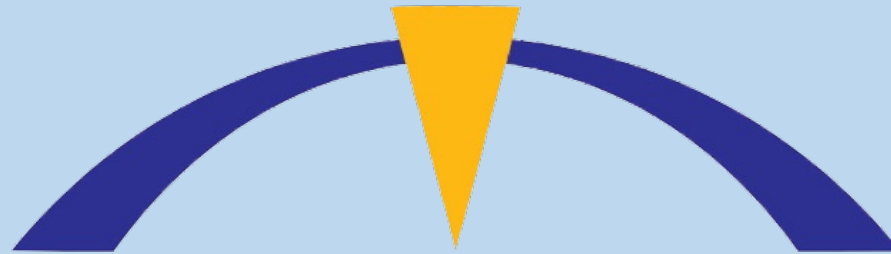
# NEXT STEPS

- **Miniaturization** of Custom Micro-Display and Optics
- **Miniaturization** of Electronics
- Smart Glasses Integration



# OUR PORTFOLIO

INTRA-KER

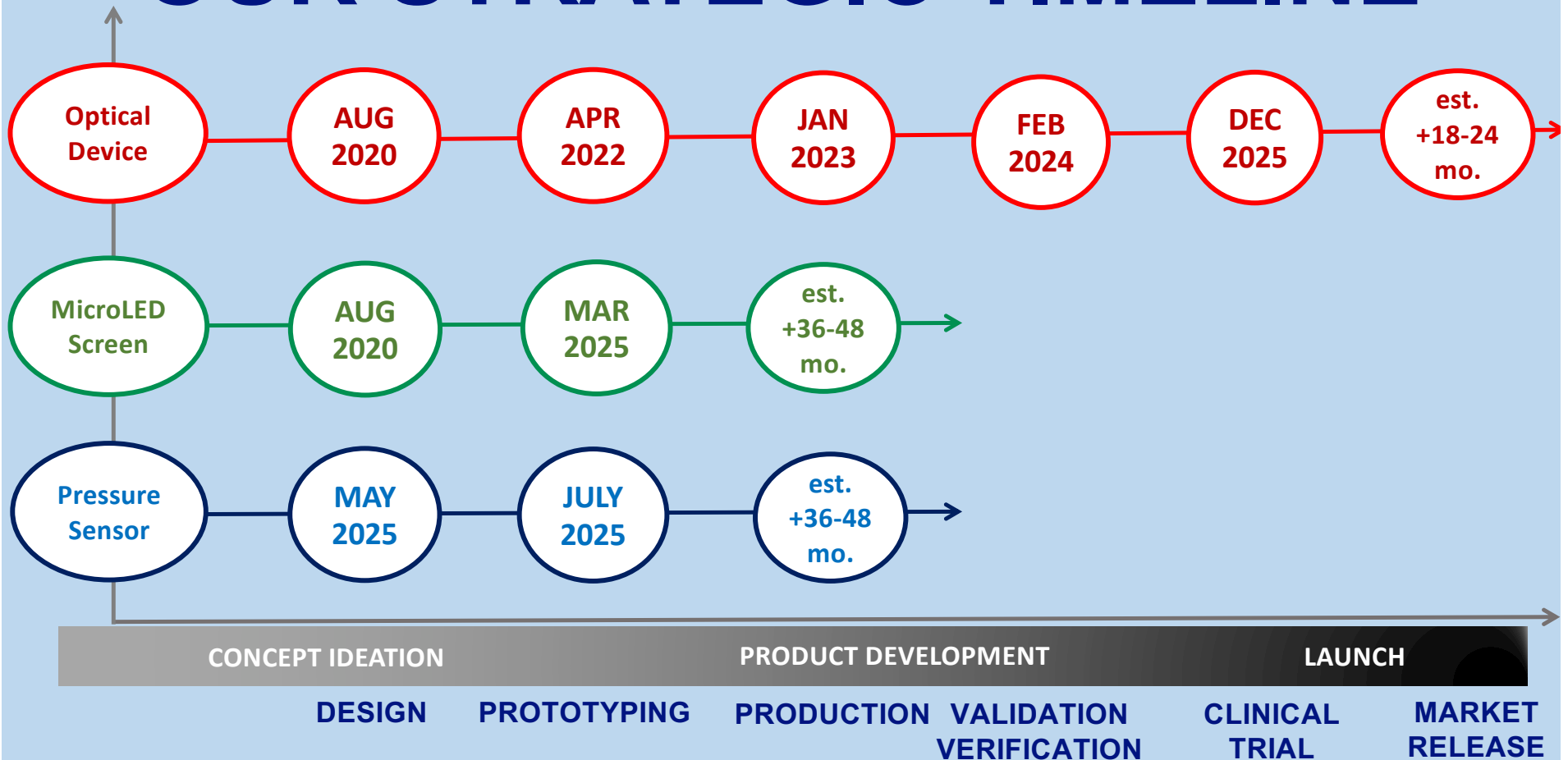


**1.OPTICAL  
DEVICE**

**2.MICROLED  
SCREEN**

**3.PRESSURE  
SENSOR**

# OUR STRATEGIC TIMELINE





**THE FUTURE OF VISION**

**WHO ARE WE?**

# INTRA-KER CORE TEAM



**Prof. Massimo Busin**  
President & CEO



**Dr. Marco Pellegrini**  
Chief Commercial Officer



**Dr. Tiziano Scalabrini**  
Chief Legal Officer



**Dr. Angeli Christy Yu**  
Chief Technology Officer

# SCIENTIFIC ADVISORY BOARD



**Dr. Diego Ponzin**



**Prof. Marco Mura**



**Prof. Teresio Avitabile**



**Prof. Vincenzo Scorgia**



**Prof. Guiseppe Giannaccare**