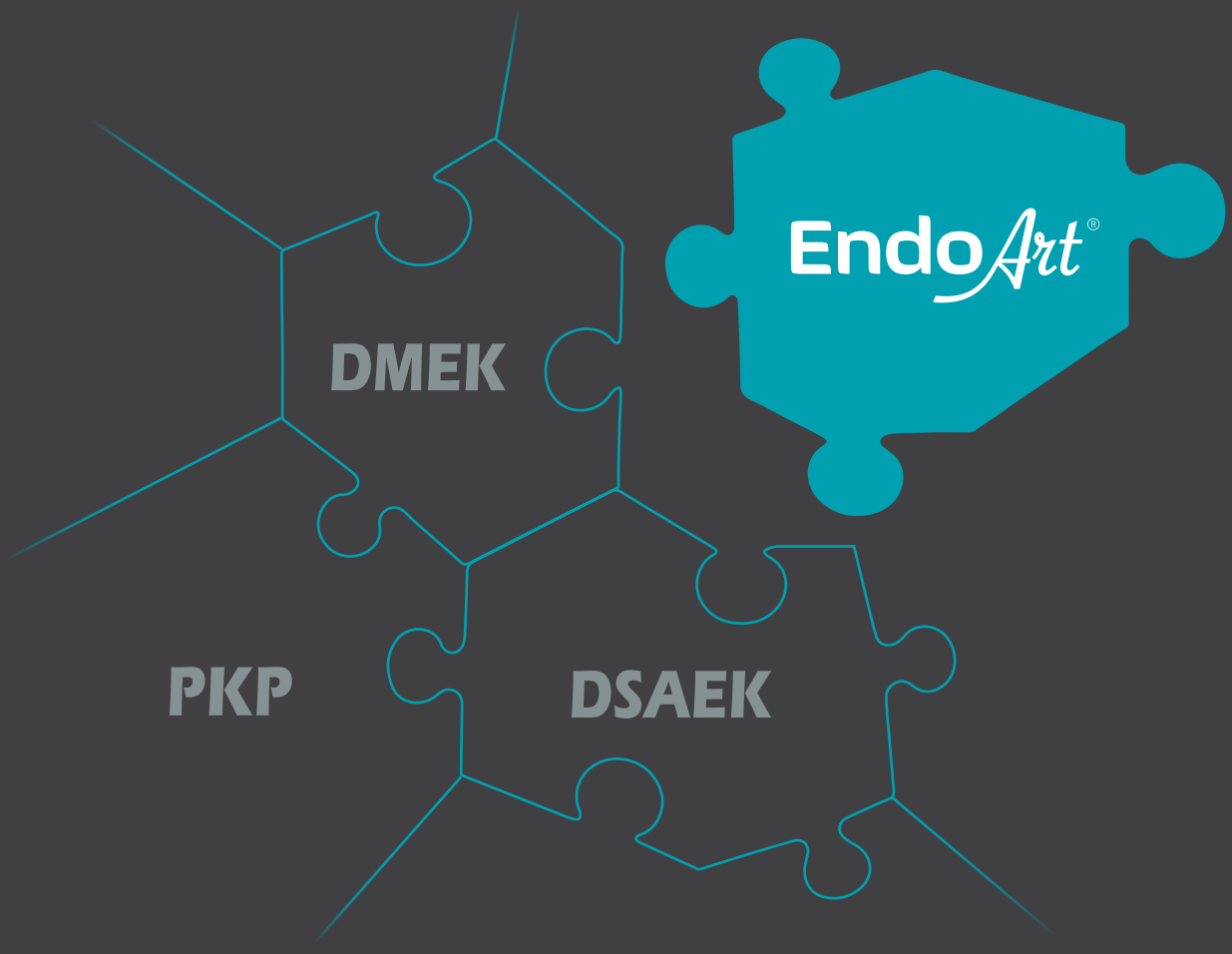
EndoArt®
Artificial Endothelial Layer

COULD ENDOART® EXPAND TREATMENT POSSIBILITIES FOR YOUR PATIENT?

A practical guide to identifying selected patients who may benefit from a donor-independent approach to chronic corneal edema



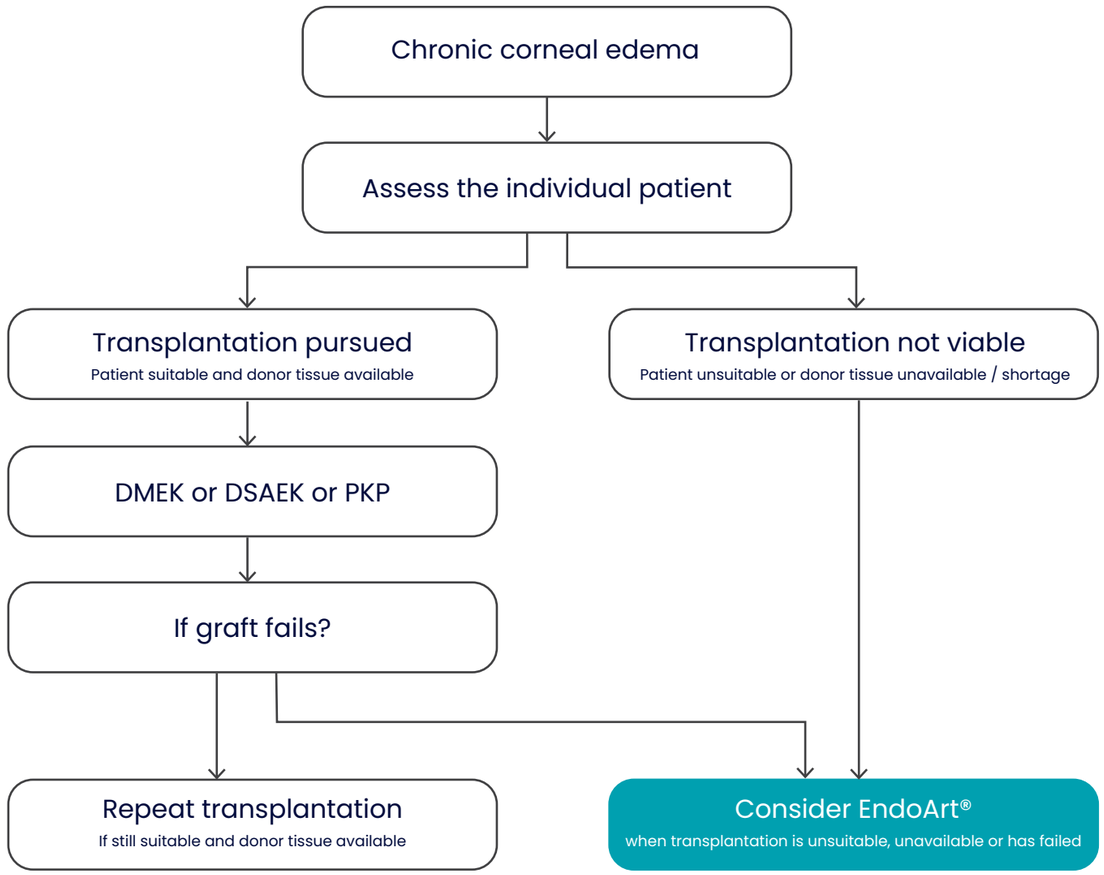
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WHEN TO REASSESS THE TREATMENT PATHWAY

Descemet Membrane Endothelial Keratoplasty (DMEK), Descemet Stripping Automated Endothelial Keratoplasty (DSAEK), and Penetrating Keratoplasty (PKP) are established donor-tissue transplantation procedures for suitable patients with corneal endothelial failure. However, transplantation may be unsuitable for some patients from the outset, while for others, graft failure or complex ocular conditions may make further transplantation unsuitable or no longer preferred. Access to transplantation may also be limited by donor-tissue availability.

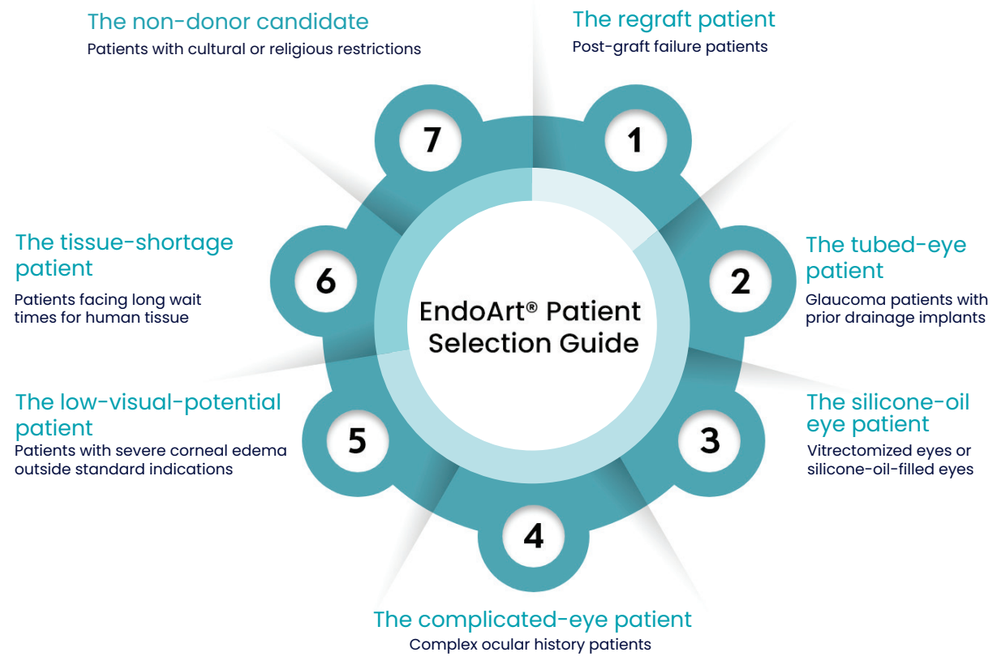
EndoArt® provides a distinct, donor-independent option for selected patients with chronic corneal edema.[1]

WHEN TO CONSIDER ENDOART®



HOW ENDOART® HELPS EXPAND TREATMENT POSSIBILITIES

EndoArt® may provide an additional, donor-independent option for selected patients with chronic corneal edema when a previous endothelial graft has failed, further transplantation may be unsuitable, or access to suitable donor tissue is limited.[2–6]



PREVIOUS DONOR-TISSUE FAILURE

1. The regraft patient - Post-graft failure patients

CLINICALLY CHALLENGING

2. The tubed-eye patient - Glaucoma patients with prior drainage implants

3. The silicone-oil eye patient - Vitrectomised eyes or silicone-oil-filled eyes

4. The complicated-eye patient - Complex ocular history patients

5. The low-visual-potential patient - Patients with severe corneal edema outside standard indications

DONOR TISSUE UNAVAILABLE OR UNSUITABLE

6. The tissue-shortage patient - Patients facing long wait times for human tissue

7. The non-donor candidate - Patients with cultural or religious restrictions

Patient profiles frequently overlap. Recognition of one or more profiles should prompt individual clinical and anatomical assessment; it does not establish suitability for EndoArt®.

WHY THESE PATIENT PROFILES MATTER

In some highly complex eyes, EndoArt® may provide a treatment pathway where further donor-tissue transplantation is not considered viable. In others, substantial reductions in corneal edema and meaningful visual improvement have been reported – outcomes considered particularly encouraging in the context of the patient's ocular complexity and prognosis.[2–6]

01 PREVIOUS DONOR-TISSUE FAILURE

The regraft patient / Previous or repeated endothelial graft failure

PATIENT PROFILE

- Persistent or recurrent corneal edema following failed DMEK or DSAEK
- Considering repeat donor grafting, with concern about its likely benefit and burden

CLINICAL EVIDENCE[3]

5 OF 7 EYES
had undergone two previous failed endothelial keratoplasty procedures, four following DSEK and one following DMEK.

28%
REDUCTION IN MEAN CCT AT 24 MONTHS

805 ± 131 µm → 577 ± 90 µm
P=0.002

- All seven implants remained in place at two years. Four eyes required rebubbling following detachment.
- Outcomes represent the complete seven-eye cohort, which included five regraft eyes.

CLINICAL RATIONALE

Donor-independent endothelial replacement[1]

- Does not depend on donor-tissue availability
- Is not subject to immune graft rejection
- Provides another potential treatment pathway following repeated endothelial graft failure

ASSESS

Previous graft history • Reason for failure • Corneal anatomy and scarring • Ocular comorbidities • Remaining visual potential • Expected benefit and burden of another graft

Abbreviation: CCT, central corneal thickness.



Dr. Alain Saad, France[2]

THE CLINICAL CHALLENGE

"In a case where multiple keratoplasties have failed, repeating another regular keratoplasty or human graft has an extremely high probability of failing again."

WHY HE CONSIDERS ENDOART®

"This is where EndoArt® has a special place. Because it is an artificial tissue, there is no risk of immune rejection."

02 CLINICALLY CHALLENGING

The tubed-eye patient / Glaucoma drainage device or previous glaucoma surgery

PATIENT PROFILE

- Corneal endothelial decompensation following glaucoma surgery, including in eyes with a glaucoma drainage device.
- Previous failed DMEK or DSAEK, with a high risk of further graft failure.
- Significant edema-related symptoms despite limited visual potential.

CLINICAL EVIDENCE[4]

12 EYES
WITH GLAUCOMA DRAINAGE DEVICES[4]

13% REDUCTION IN MEAN CCT AT **SIX WEEKS**

719 ± 146 µm → 622 ± 175 µm
P=0.004

IMPROVEMENT IN MEAN BSCVA AT **12 WEEKS**

1.6 ± 0.5 → 1.1 ± 0.6 logMAR
P=0.028

- Nine eyes had previously undergone DMEK; eight had undergone at least two DMEK procedures.
- Four eyes required at least one rebubbling.
- One implant was explanted.

ASSESS

Inflammatory or membrane-forming tendency • Iris-lens diaphragm integrity • Posterior corneal regularity • Visual potential and edema-related symptoms • Prior glaucoma surgery or drainage device • Previous endothelial graft history

Abbreviation: BSCVA, best spectacle-corrected visual acuity.



Professor Björn Bachmann, Germany[2]

THE CLINICAL CHALLENGE

"In particular, patients after glaucoma drainage device implantation have a transplant failure rate exceeding 50% within a few years, even when the tube does not come into contact with the corneal endothelium."

WHY HE CONSIDERS ENDOART®

"EndoArt® offers the fundamental advantage of eliminating the risk of rejection. We use this device in patients with limited visual potential who nonetheless suffer significantly from corneal endothelial decompensation and the associated edema."

PHYSICIAN INSIGHT

"The best outcomes have been seen in patients without a tendency toward inflammatory reactions or membrane formation. The implantation works best when the iris-lens diaphragm is intact, and the posterior corneal surface is regular."

03 CLINICALLY CHALLENGING

The silicone-oil eye patient / Complex vitreoretinal history with corneal decompensation

PATIENT PROFILE

- Complex vitreoretinal history, often involving trauma or revisional surgery, with corneal decompensation
- Current or planned silicone-oil use or exchange
- Aphakia or absence of an intact iris-lens diaphragm
- Opaque cornea limiting visualisation for vitreoretinal surgery

PUBLISHED CLINICAL EXPERIENCE

Individual published cases in previously vitrectomised eyes reported:

911 µm → 691 µm[5]
CCT at 12 months, with resolution of epithelial bullae

859 µm → 651 µm[6]
CCT at three years

These numerical outcomes are from individual published cases and are separate from Prof. Szurman's 14-case experience.

ASSESS

Vitreoretinal history and planned surgery • Silicone-oil status • Aphakia or iris-lens diaphragm integrity • Corneal clarity for posterior-segment visualisation • Posterior corneal regularity • Need for additional fixation



Professor Peter Szurman, Germany[2]

THE CLINICAL CHALLENGE

"We know that the combination of penetrating keratoplasty in aphakic eyes with silicone oil leads to a survival rate of less than 10% in these eyes after one year. Without an iris lens diaphragm, especially, this has a bad survival rate for corneal transplant."

WHY HE CONSIDERS ENDOART®

"Nobody had thought to use EndoArt® in combination with silicone oil, but it can be perfectly employed in these situations. In anterior segment surgery, you have alternatives, but in these complex vitreoretinal cases with opaque cornea, ***there was no viable alternative until EndoArt®****."*

14 COMPLEX CASES

"We began using EndoArt® in 14 complex cases, more than half being trauma cases with revisional surgeries, silicone oil exchange, and a decompensation of the cornea."

PHYSICIAN INSIGHT

"One thing I would add is that if the posterior surface of the cornea is irregular, you need to use three to six sutures instead of the usual one suture to firmly attach the EndoArt®."

04 CLINICALLY CHALLENGING

The complicated-eye patient / Multiple ocular comorbidities and previous anterior-segment procedures

PATIENT PROFILE

- Multiple previous anterior-segment procedures, including endothelial grafting and glaucoma surgery/device
- Endothelial graft decompensation with ocular hypertension
- Retinal comorbidities limiting visual prognosis

The 78-year-old patient also presented with pseudoexfoliative glaucoma, cornea guttata, cystoid macular edema and an epiretinal membrane, and had undergone combined phaco-DMEK, multiple filtering procedures and Paul valve implantation.

PHYSICIAN-REPORTED COURSE

Multiple reinjections and adapted fixation

- The implant was initially secured with three stitches.
- Detachment occurred despite tamponade with an air–SF6 gas mixture.
- Two reinjections were performed.
- A further injection and additional stitch were required because of a persistent paracentral fold.
- At 1.5 months, three of the four stitches were removed during a fourth injection.

This case demonstrates that implantation may be straightforward, while achieving durable attachment can require repeated postoperative intervention and adjustment of the fixation strategy.

ASSESS

Previous ocular procedures and graft history • Cause of graft decompensation • Glaucoma device and IOP status • Corticosteroid-related IOP risk • Retinal comorbidities and functional prognosis • Attachment and fixation strategy • Capacity for postoperative follow-up and positioning

Abbreviations: IOP, intraocular pressure; SF6, sulfur hexafluoride



Dr. Diane Bernheim, France[2]

THE CLINICAL CHALLENGE

"All these anterior segment surgeries and ocular hypertension were responsible for cell loss in the DMEK graft, leading to decompensation."

WHY SHE CONSIDERS ENDOART®

"I chose to perform EndoArt®, given the patient's limited functional prognosis and the risk of limited endothelial graft life. The advantage of EndoArt® in this case is the absence of cell loss, rejection, and the reduced use of long-term corticosteroids, thus limiting the rise in ocular tension."

"At 1.5 months, the patient still presented with a graft fold, so I removed three of the four stitches during the fourth injection, and this action allowed for a lasting bond."

PHYSICIAN INSIGHT

"The implantation was performed without difficulty. I sutured the graft with three stitches."

05 CLINICALLY CHALLENGING

The low-visual-potential patient / Symptomatic corneal edema where substantial visual improvement may be limited

PATIENT PROFILE

- Persistent corneal edema or bullous keratopathy
- Limited visual potential due to ocular comorbidities
- Previous endothelial graft failure or high anticipated risk of further donor-graft failure

DEFINE THE TREATMENT OBJECTIVE

✓ Reduce corneal edema
✓ Resolve bullous keratopathy
✓ Improve comfort
✓ Support visual improvement where potential remains

PUBLISHED LONG-TERM EXPERIENCE

One published case with limited visual potential was followed for six years[6]:

32%
REDUCTION IN CCT

730 µm → 496 µm
Baseline to six years

2.3 → 1.8 logMAR
CDVA at six years

Visual potential was limited by pre-existing optic and central retinal atrophy.

ASSESS

Cause of limited visual potential • Edema severity and symptoms • Previous graft history • Glaucoma/tube status · Retinal and optic-nerve status • Treatment objectives • Patient expectations

Abbreviation: CDVA, corrected distance visual acuity.



Mr. Romesh Angunawela, UK[2]

THE CLINICAL CHALLENGE

"A patient with iridocorneal endothelial (ICE) syndrome, where a previous DS(A)EK had failed after 12 months (the eye also had an aqueous drainage tube), was keen to improve her vision."

WHY HE CONSIDERS ENDOART®

"Given the high likelihood of tissue failure in an eye with ICE syndrome, she chose to have EndoArt® on the basis that the device could not be rejected or fail due to ICE cellular behaviour or glaucoma related complications."

PHYSICIAN PERSPECTIVE

"EndoArt® offers a solution that will, in theory, survive the evolving anterior chamber microenvironment of an eye with ICE syndrome, and hope to the patient where other surgeries have failed and are likely to fail. Once the EndoArt® is attached, these eyes are more comfortable as bullous keratopathy resolves. Some patients will perceive subjective visual improvement."

06 DONOR TISSUE UNAVAILABLE OR UNSUITABLE

The tissue-shortage patient / When access to suitable donor tissue is limited, delayed or unpredictable

PATIENT PROFILE

- Chronic corneal edema causing pain or visual impairment
- Delayed, unpredictable or unavailable access to suitable donor tissue
- Risk that further delay may worsen symptoms, corneal clarity or visual potential
- Complex corneal anatomy that may limit further transplantation

Prof. Alain Saad, France[2]

"I also use EndoArt® as a temporary treatment for patients on the waiting list for the DMEK procedure. In some advanced cases, long wait time might decrease the final best corrected visual acuity because a chronic severe corneal edema can lead to corneal fibrosis. An EndoArt® can prevent such a complication while waiting for a DMEK graft."

ASSESS

Donor-tissue availability • Anticipated waiting time • Clinical significance of further delay • Severity and duration of edema • Painful bullae • Corneal fibrosis or scarring • Visual potential • Suitability for further transplantation • Intended treatment pathway • Patient expectations



Professor David Lockington, UK[2]

THE CLINICAL CHALLENGE

"In the UK (and elsewhere), demand for corneal transplantation greatly outweighs tissue availability."

WHY HE CONSIDERS ENDOART®

"EndoArt® offers an immediate, off-the-shelf solution to long wait times and the hope of relieving pain and better vision sooner."

PHYSICIAN-REPORTED PATHWAYS

"Increasingly, what was intended as a temporising intervention until human tissue became available has become a quicker, semi-permanent solution in patients with complex edematous corneas who may not be able to wait many months for DMEK tissue."

07 DONOR TISSUE UNAVAILABLE OR UNSUITABLE

The non-donor candidate / Cultural, religious or ethical restrictions concerning human donor tissue

PATIENT PROFILE

- Chronic corneal edema requiring treatment
- Unable or unwilling to accept human donor tissue
- Cultural, religious or ethical restrictions concerning transplantation
- Interest in a synthetic, donor-independent treatment pathway
- Suitable clinical and anatomical profile for EndoArt®

PHYSICIAN-REPORTED OUTCOME[2]

ONE YEAR POSTOPERATIVELY

APPROXIMATELY 45% REDUCTION IN CENTRAL PACHYMETRY

>1000 µm → 550 µm

"A year postoperatively, the patient is doing well – she can see more shapes, colours, and, most importantly, her daughter's face."

The patient was also being fitted with aphakic contact lenses to pursue further visual improvement.

PHYSICIAN TECHNICAL INSIGHT

Because of the patient's ocular anatomy, Prof. Ní Dhubhghaill adapted the fixation technique:

"Given the singular ocular chamber, we fixated the EndoArt® with an anchor suture so that when it was inserted, it would not fall to the posterior chamber."

The implant was subsequently lifted with air and secured with three corneal sutures, which were removed three months postoperatively.

ASSESS

Previous graft history and reason for failure • Monocular status • Acceptability of immunosuppression • Anterior-chamber anatomy and posterior-dislocation risk • Fixation strategy • Visual potential • Patient priorities and follow-up capacity



Professor Sorcha Ní Dhubhghaill, Belgium[2]

THE CLINICAL CHALLENGE

"A 26-year-old patient from Morocco was born with congenital glaucoma. She lost an eye at an early age, and her remaining eye went through multiple surgeries, including full-thickness corneal transplantations that had been rejected twice."

WHY SHE CONSIDERS ENDOART®

"We discussed immunosuppression, but the patient, with one child, did not want to risk infertility and the side effects. She was very receptive to the EndoArt® option. The biggest advantage was that there was no requirement for immunosuppression and a chance for long-term improvements."

FOLLOW-UP CONSIDERATION

"Her central pachymetry reduced from over 1000 µm to 550 µm, but we still recommend regular evaluations to ensure the cornea does not dehydrate too much."

WHEN TO CONSIDER ENDOART®?

The seven physician-informed profiles reflect three recurring, sometimes overlapping clinical situations: donor tissue unsuitable or unavailable, clinically challenging cases, and previous donor-tissue failure. Use the framework below to support assessment of your own patient, considering the complete clinical picture, treatment history and intended treatment objective.

IDENTIFY the context

Previous graft failure • Barriers to donor tissue • Glaucoma drainage device or surgery • Complex vitreoretinal history • Multiple ocular comorbidities • Limited visual potential

↓

DEFINE the objective

Reduce chronic corneal edema • Support corneal clearing • Relieve painful bullae • Pursue visual improvement where potential remains • Provide a donor-independent pathway

↓

ASSESS patient suitability

Treatment history • Corneal anatomy and scarring • Iris–lens diaphragm integrity • Glaucoma and IOP control • Retinal and optic-nerve status • Visual potential • Fixation requirements • Follow-up capacity

↓

DISCUSS with the patient

Treatment objectives • Potential benefits and limitations • Alternative pathways • Potential need for rebubbling or further intervention • Follow-up requirements

Each patient requires individual clinical and anatomical assessment in accordance with the current Instructions for Use[1].

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EndoArt®
Artificial Endothelial Layer

ENDOART® EXPANDS TREATMENT POSSIBILITIES

For selected patients with chronic corneal edema, EndoArt® may offer a donor-independent option when the conventional donor-tissue pathway is unavailable or may no longer be appropriate.

COULD YOUR PATIENT BENEFIT?

✓ Reduce chronic corneal edema[3-6]

✓ Offer another path when transplantation is challenging

✓ Plan treatment without dependence on donor-tissue availability[1]



WITH THANKS TO THE PHYSICIANS WHO SHARED THEIR EXPERIENCE

EyeYon Medical gratefully acknowledges the physicians whose clinical perspectives contributed to this patient-profile guide: Prof. Alain Saad · Prof. Björn Bachmann · Prof. Peter Szurman · Prof. Diane Bernheim · Mr. Romesh Angunawela · Prof. David Lockington · Prof. Sorcha Ní Dhubhghaill

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Consult the current Instructions for Use for approved indications, contraindications, warnings and precautions. Product availability may differ by country.

Rev.1.0