AMNIOTIC MEMBRANE THERAPY

Patient Information & Consent Form

Patient name: _____ Date of birth: _____

Clinic: _____ Treating practitioner: _____

Eye(s): ■ Right ■ Left ■ Both Treatment date: _____

Reason for treatment / diagnosis: _____

About the treatment

Amniotic membrane therapy (AMT) involves placing a specially processed membrane from donated human placental tissue on the surface of the eye. The membrane is used to support healing of the cornea and ocular surface. Your eye-care practitioner will place the membrane and may use a bandage contact lens to help keep it in place.

Potential benefits and treatment limitations

The treatment may help protect the ocular surface, support tissue healing and reduce inflammation or discomfort. Results vary depending on your eye condition and response to treatment. Complete healing, improved vision or symptom relief cannot be guaranteed. Additional medication, repeat treatment or another procedure may be needed.

Possible risks and side effects

As with any eye procedure, there are potential risks. These may include:

- Temporary irritation, redness, tearing, discomfort, light sensitivity or blurred vision.
- Movement, folding, early loss or breakdown of the membrane.
- Inflammation, infection, delayed or incomplete healing, or worsening of the original eye condition.
- Corneal scarring or changes in vision, which in severe cases may be lasting.
- Uncommon reactions to materials or medicines used during treatment.
- A small residual possibility of disease transmission from donated human tissue despite donor screening, testing and processing safeguards.

Your practitioner may discuss additional risks that are specific to your eye condition.

Other treatment options

My practitioner has discussed reasonable alternatives to this treatment, including the option not to proceed, and the possible consequences of declining treatment, as relevant to my condition.

What to expect and care after treatment

Vision may be blurry and the eye may feel irritated for a period after placement. The membrane may gradually break down or dissolve as healing occurs. Follow the instructions given by your treating clinic:

- Do not rub the treated eye or attempt to remove or reposition the membrane or any bandage contact lens.
- Use prescribed drops or medications as directed.
- Attend follow-up appointments as instructed.
- Contact your treating eye-care clinic promptly if pain, redness, discharge, light sensitivity or vision becomes worse. Seek urgent eye care if the clinic cannot be reached.

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Patient Consent & Practitioner Confirmation

Patient acknowledgment and consent

I understand that amniotic membrane therapy has been recommended for my eye condition. My treating practitioner has explained the purpose of treatment, its expected benefits and limitations, its important risks and side effects, and reasonable alternatives. I understand that results are not guaranteed.

I understand the information above, including the basic care instructions and symptoms that require prompt attention. I have been able to ask questions and have received answers that I understand. I voluntarily agree to proceed with amniotic membrane therapy for the eye(s) indicated on this form.

Patient / substitute decision-maker name: _____

Signature: _____ Date: _____

If signed by a substitute decision-maker, relationship / authority: _____

Practitioner confirmation

I have discussed the nature and purpose of the proposed treatment, expected benefits, material risks, reasonable alternatives and the consequences of not proceeding as appropriate to this patient. I have answered the patient's or substitute decision-maker's questions.

Practitioner name: _____

Practitioner signature: _____ Date: _____

Notes specific to this patient (optional)

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This form supports, but does not replace, the informed-consent discussion between the patient and treating practitioner. The practitioner should adapt the discussion and written instructions to the patient and the applicable product instructions for use.