

FOR TRAINING PURPOSES ONLY | NOT TO BE DISTRIBUTED EFFECTIVE MAY 2023

CLINICAL, PROCEDURAL & BUSINESS OVERVIEW TRAINING



Additional Training Information

WHEN PRESCRIBING OPHTHALOGIX AMT

Patients should be sufficiently screened for conditions that may exacerbate normal ocular wound healing response, worsen underlying disease symptoms, and/or prolong healing time.

Such as:

- Symptoms/ history of ocular herpes
- Treatment of cancer
- Diabetes and other systemic disease
- Disorders of collagen metabolism

Patients who are smokers are at a higher risk of adverse reaction/reduced treatment outcomes following amnion graft placement compared to non-smokers.

Patients should always discuss any medications they are taking with medical professionals before the graft placement as some may result in a slower than expected wound healing response.





Additional Training Information

INSTRUCTIONS FOR HANDLING AND POST-PROCEDURE CARE

- Proper care should be taken before application of the graft. Gloves and any other
 materials used during the application must be clean and sterile before the procedure to
 avoid contamination.
- Cornea must be dried thoroughly before placement to stabilize and prevent graft movement.
- Appropriate sizing of the graft is necessary to prevent graft dislocation. The graft only needs to be large enough to cover the defect. The graft is not required to cover the entire corneal surface.
- No more than one graft should be placed in the eye during a treatment session. Placing
 multiple grafts during a single treatment session may cause pain and intensify patient
 immune response.
- Due to the translucent nature of the amnion disc, patients may experience blurred vision and should be advised against operating vehicles or machinery for a few hours after the procedure.
- Patients must be advised on post-procedural care to avoid any complications as any
 airborne contaminates (e.g., allergens, mold, smoke, dust, and debris) can negatively
 impact patient outcomes. Patients should refrain from water related activities until the
 treatment is complete, as water can carry microorganisms that lead to infection of the
 eye. If any problems arise, the patient must contact an eye care professional immediately.





Additional Training Information

MEDICAL PROFESSIONALS MUST BE ADVISED OF THE FOLLOWING WARNINGS PRIOR TO PROCEDURE

- Appropriate sizing of the bandage contact lens is necessary to prevent complications. A tight fitting BCL may cause oxygen deprivation. A loose fitting BCL may cause physical interference of the re-epithelialization. Review complications listed for the bandage contact lens used with the graft.
- Patients should be warned of the following potential issues including pain, discomfort, feeling of foreign body, blurred vision and other immune responses may occur when undergoing amnion graft treatment which are acceptable in a small scale and typically dissipate within 24-48 hrs. If a patient is not tolerating the graft, the graft should be removed.
- Amnion grafts are treated with ethanol and air dried. Trace amounts of ethanol may be present on the grafts.
- There is no FDA indication for use of this graft.
- The above factors must be considered carefully by the physician before proceeding with amnion graft treatment.

