



ADVERSE EVENT / REACTION REPORTING FORM

(As per R182: Regulations Relating to the Use of Human Biological Material)

1. Reporting Information

- Date of Report: _____
- Reported by (Name & Surname): _____
- Role/Position: _____
- Institution: _____
- Contact Number: _____
- Email: _____

2. Donor / Tissue Product Information

- Tissue Type: ☐ Amniotic Membrane (hAM)
- Batch / Lot Number: _____
- Date of Receipt: _____
- Date of Use: _____

3. Recipient / Patient Information (*confidential – anonymise where required*)

- Patient Identifier (Hospital only): _____
 - Age: _____ Gender: ☐ M ☐ F
 - Date of Implantation / Use: _____
 - Clinical Indication: _____
 - Treating Surgeon / Physician: _____
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4. Description of the Adverse Event / Reaction

- Date of Onset: _____
- Nature of Event:
 - ☐ Infection
 - ☐ Inflammation
 - ☐ Graft Failure / Rejection
 - ☐ Toxicity / Chemical Reaction
 - ☐ Other (specify): _____
- Detailed Description (signs, symptoms, lab findings, surgical observations):

- Severity:
 - ☐ Mild (no intervention required)
 - ☐ Moderate (medical intervention required)
 - ☐ Severe (life-threatening / permanent damage)
 - ☐ Death

5. Clinical Outcome

- ☐ Resolved without sequelae
- ☐ Resolved with sequelae
- ☐ Ongoing
- ☐ Fatal (Date of Death: _____)



For Tissue Bank use only:

1. Investigations Performed

- Microbiological Cultures: _____
 - Histopathology: _____
 - Other Tests: _____
 - Results Summary:
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2. Root Cause Analysis

- Possible link to tissue product? ☐ Yes ☐ No ☐ Uncertain
 - Potential contributing factors:
 - ☐ Donor factors
 - ☐ Processing / Storage error
 - ☐ Distribution / Transport failure
 - ☐ Clinical use error
 - ☐ Other: _____
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3. Corrective and Preventive Actions (CAPA)

- Actions Taken: _____
 - Preventive Measures Implemented: _____
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4. Reporting to Regulatory Authorities

- Date reported to SAHPRA / Department of Health: _____
 - Reference Number (if issued): _____
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5. Sign-Off

- Name & Signature of Reporter: _____
- Date: _____
- Tissue Bank Responsible Person (Designated Individual): _____