Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	350670 Amnion - Surgical BioFix Ltd
ARTG entry for	Biological Included Class 2
Sponsor	Surgical BioFix Ltd
Postal Address	PO Box 11, Coorparoo, QLD, 4151 Australia
ARTG Start Date	3/12/2020
Product Category	Included Class 2
Status	Active
Approval Area	Biologicals

Products

1 . Foetal membranes, freeze-dried, irradiated - L - Revita

Product Type	Amnion	**Effective Date**	26/02/2021
Intended Use	To be used as a wound covering, or barrier membrane over chronic and acute wounds, including dermal ulcers or defects		

Specific Conditions

1. The actual date of commencement of supply of the good after inclusion under Part 3-2A of the Act must be notified to the Director, Biological Sciences Section of the TGA. Please note the definition of 'supply' in subsection 3(1) of the Act for this purpose.

2. To confirm the stability of the Revita allografts, the submission of reports detailing the storage and stability validation data shall be provided to the TGA for review. Unless agreed separately between the Sponsor who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than 12 calendar months after the date of this letter. The subsequent reports must be submitted no less frequently than annually from the date of the first submitted report until the period of the proposed shelf life of the product is covered.

3. Validation of transportation between Surgical Biofix and Steritech Pty Ltd must be validated to ensure product temperature is maintained throughout the process. This validation study must be provided to the TGA no later than 12 calendar months after the date of this letter.

4. Provision of batch analysis data for the first three batches of Revita shall be provided to the TGA for review. Unless agreed separately between the Sponsor who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than 12 calendar months after the date of this letter.

Components

1 . Component Description

Dosage Form	Graft
Route of Administration	Topical
Visual Identification	

Active Ingredients

Amnion	**1 U**