



**URGENT RECALL FOR PRODUCT CORRECTION**

**Cook® Biodesign® 1-Layer Tissue Graft and Cook® Biodesign® 4-Layer Tissue Graft**  
 (Cook Biotech - ARTG: 153047)  
 TGA Reference: RC-2017-RN-00328-1

7/04/2017

**Attention:** Chief Executive Officer, Head of Surgery

This notification is to inform you, as a user of the Cook Biodesign® 1-Layer and/or 4-Layer Tissue Graft, of a planned change in the Intended Use wording of the product instructions for use. This change is in response to the report of two potential adverse events during use in Urological or Gynecological procedures.

This Product Correction notice provides clarification of the product’s intended use as follows:

Previous Intended Use	Updated Intended Use
The Cook® Biodesign® Tissue Graft is intended for implantation to reinforce soft tissue. The graft is supplied sterile in peel-open packages and is intended for one-time use.	The Cook® Biodesign® Tissue Graft is intended for implantation to reinforce soft tissue. The graft is supplied sterile in peel-open packages and is intended for one-time use.  This device is not intended for use in urological or gynaecological procedures.

Model #s

Cook® Biodesign® 1-Layer Tissue Graft	
C-SLH-1S-2X3 C-SLH-1S-7X10	SLH-1S-7X10

Model #s

Cook® Biodesign® 4-Layer Tissue Graft		
C-SLH-4S-1X10	J-SLH-4S-7X20	SLH-4S-2X3
C-SLH-4S-2X3	J-SLH-4S-4X7	SLH-4S-3.5X5
C-SLH-4S-4X7	J-SLH-4S-7X10	SLH-4S-4X7
C-SLH-4S-7X10		SLH-4S-7X10
C-SLH-4S-7X20		SLH-4S-7X20

**The product is safe for use within the above updated intended use and need not be returned. A new version of the instructions for use that includes the updated intended use will be introduced within the next few months. In the interim, each device will be supplied with a leaflet that includes notice of the update.**

If you have any questions regarding this clarification of the package instruction wording, please contact your Cook Representative on 1800 777 222 for further information.

This action is being undertaken after consultation with the Therapeutic Goods Administration.

Sincerely,



Katie-Lou Buscher  
Regulatory Affairs Manager  
William A. Cook Australia Pty. Ltd.