



# Medical Device Details

Sponsor: CARSL Consulting  
P O Box 480  
Pukekohe  
Auckland  
New Zealand

WAND Reference: 160215-WAND-6LG8BC

Sponsors Own Reference: Safe Obstetric Systems Pty Ltd - Foetal membrane manipulator

GMDN: Foetal membrane manipulator [47978]

Class: I - Sterile

Intended Purpose: An inflatable 'pillow' that is inserted via the vagina, used to cushion and raise the head of the foetus during a caesarian section following unsuccessful vaginal birth. The cushion is inflated using a manual syringe.

Manufacturer: Safe Obstetric Systems 32 Hillwood Grove  
Brentwood  
Essex  
UNITED KINGDOM

ARTG ID: 225818

- ☐ > The device is supplied sterile.
  - > Sterilisation method: Ethylene oxide
- > The device is intended to be invasive.
- > The device is intended for single use.
- > The device is not an active device.
- > The device does not contain material or ingredients of microbial origin.
- > The device does not contain material or ingredients of recombinant origin.
- > The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.
- > The device does not contain material or ingredients of human origin.

- The device does not contain human blood or its components.
- The device consists of: Single product
- The device does not contain material or ingredients of animal origin.
- The device is not medicated.
- The device is not formulated.
- The product does not contain a medicine that has consent for marketing in New Zealand.
- The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

Status: Active