



Medical Device Details

Sponsor:	Ossur New Zealand Limited 6/80 Westpoint Drive Hobsonville Auckland New Zealand
WAND Reference:	211222-WAND-6Y6BBQ
Sponsors Own Reference:	Prosthesis suspension system
GMDN:	External lower-limb prosthesis suspensory component, non-powered [64715]
Class:	I
Intended Purpose:	Devices used to hold/fasten a prosthetic to the body. Some variants provide airtight interface between atmosphere and inner socket volume in order to provide a suction suspension to a prosthetic. Includes air, lanyard and mechanical locking systems. Some variants are mechanical vacuum pumps intended for vacuum assisted prosthetic suspension, activated during gait. Some variants produce a definitive prosthetic socket using casting liner, material and tool kits.
Manufacturer:	Ossur HF Grjothals 5 Reykjavik Iceland
ARTG ID:	308054
	<ul style="list-style-type: none"> > The device is supplied unsterilised. > The device is not intended to be invasive. > The device is not 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