



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	316221	Connexion Surgical Pty Ltd - Spinal cage
<b>ARTG entry for</b>	Medical Device Included Class IIb	
<b>Sponsor</b>	Connexion Surgical Pty Ltd	
<b>Postal Address</b>	12 Finch Avenue, Concord, NSW, 2137 Australia	
<b>ARTG Start Date</b>	5/04/2019	
<b>Product Category</b>	Medical Device Class IIb	
<b>Status</b>	Active	
<b>Approval Area</b>	Medical Devices	

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

Name	Address
Neo Medical SA	Route de Lausanne 157 A 1096 Villette , Lavaux, Switzerland

### Products

#### 1 . Spinal cage

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	5/04/2019
<b>GMDN</b>	38161 Spinal cage		
<b>Intended Purpose</b>	Intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. To be used with bone graft material packaged within the implant to facilitate interbody fusion and to be used with supplemental spinal fixation systems that have been cleared for the use in the lumbosacral spine. For Degenerative Disc Disease (DDD) at one or multiple levels from L2 to S1. These DDD patients may also have grade 1 and potentially grade 2 or 3 Spondylolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.		
<b>Product names</b>	Neo Cage System		

### Specific Conditions

No Specific Conditions included on Record

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