



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 97288 Medical Specialties Australasia Pty Ltd - Mesh, surgical

**ARTG entry for** Medical Device Included Class IIb  
**Sponsor** Medical Specialties Australasia Pty Ltd  
**Postal Address** PO Box 764, WILLOUGHBY, NSW, 2068  
 Australia  
**ARTG Start Date** 29/09/2003  
**Product Category** Medical Device Class IIb  
**Status** Active  
**Approval Area** 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
pfm medical titanium GmbH	Sudwestpark 42 , Nurnberg, 90449 Germany

**Products**

**1 . Mesh, surgical**

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	29/09/2003
<b>GMDN</b>	16048 Mesh, surgical		
<b>Intended Purpose</b>	Soft tissue support		

Exception(s) to approval	Start	Exception product description	Reason	Notification
Active	12/08/2015	TiLOOP Tape TiLOOP Two TiLOOP Total 4 TiLOOP Total 6 TiLOOP Fix TiLOOP Mesh TiLOOP Patch TiLOOP Clip	Product excluded by regulatory activity	The Secretary is satisfied that the safety and performance of a device included in the entry are unacceptable. However, as other devices of the same kind are included under the ARTG entry, the entry has been varied to exclude these devices.

**Specific Conditions**

No Specific Conditions included on Record

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