



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

**Public Summary**

**Summary for ARTG Entry:** 199649 Ossur Australia Pty Ltd - Spine thermoplastic splint system

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** Ossur Australia Pty Ltd  
**Postal Address** 26 Ross Street, NORTH PARRAMATTA, NSW, 2151  
 Australia  
**ARTG Start Date** 31/07/2012  
**Product category** Medical Device Class 1  
**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**

Spinal Solutions Inc

**Address**

1971 Old Covington Road NE STE 103  
 Conyers, GA, 30013  
 United States Of America

**Products**

**1. Spine thermoplastic splint system**

<b>Product Type</b>	Single Device Product	<b>Effective date</b>	31/07/2012
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**GMDN** 58757 Spine thermoplastic splint system

**Intended purpose** Body Jacket Spinal Orthosis for spinal immobilisation

**Specific Conditions**

No Specific Conditions included on Record

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Public Summary