# Recall detail

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|---|---|
| Type of Product[i] | Medical Device |
| TGA Recall Reference[ii] | RC-2013-RN-01262-1 |
| Product Name/Description[iii] | Viscocel and Viscocel Plus (Hydomethylpropcellulose) 2% Prefilled Syringes 1.5mL and 2.0mL<br><br>Product Codes: AusVIS15, AusVIS20<br><br>Batch Numbers: 13D02 (expiry 04/2015), 12A13 (expiry 01/2015), 12J08 (expiry 10/2014), 13B18 (expiry 02/2015), 12J02 (expiry 10/2014), 12G16 (expiry 07/2014), 12I04 (expiry 09/2014) and 12H20 (expiry 08/2014)<br><br>Manufactured from September 01, 2011 to September 19, 2013<br><br>ARTG Number: 132648 |
| Recall Action Level[iv] | Hospital |
| Recall Action Classification[v] | Class I |
| Recall Action Commencement Date[vi] | 6/12/2013 |
| Responsible Entity[vii] | Boucher & Muir Pty Ltd |
| Reason / Issue[viii] | Inspections findings by the FDA noted deficiencies in the quality system regulations for medical device manufacturers relating to sterility and biocompatibility that may result in the release of contaminated products. No injuries have been reported for ViscoCel, however several cases of endophthalmitis reported to a related viscoelastic product in 2011 manufactured at the same facilities. |
| Recall Action[ix] | Recall |
| Recall Action Instructions[x] | Boucher & Muir is advising users to quarantine all units of the affected batches. Boucher & Muir is recovering affected stock and a credit note issued. |
| Contact Information[xi] | 1800 627 680 - Boucher & Muir |

## Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the