Recall detail

Type of Product	Medical Device
TGA Recall Reference	RC-2016-RN-00206-1
Product Name/Description	Verso Shoulder Forked Retractor (Comprehensive Instrumentation (2 Prong Retractor)) Part number: 402852 All Lots affected ARTG Number: 177811
Recall Action Level	Hospital
Recall Action Classification	Class II
Recall Action Commencement Date	24/02/2016
Responsible Entity	Biomet Australia Pty Ltd
Reason / Issue	An investigation has identified that Verso Shoulder Forked Retractor Part Number 402582 was manufactured using 420 stainless instead of 420 S29 stainless steel. 420 stainless steel is more brittle than 420 S29. The instrument may fracture during use. If the retractor fractures during surgery, surgical intervention may be necessary to retrieve any fractured pieces. A delay in surgery greater than 30 minutes may occur. If the pieces are unable to be retrieved, the patient would retain a foreign body.
Recall Action	Recall
Recall Action Instructions	The sponsor is advising users to inspect stocks and quarantine the affected units. The sponsor will remove and replace the affected units.
Contact Information	02 9483 5426 - Zimmer Biomet

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 risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.
- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.