Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-01366-1
Product Name/Description[iii]	Cheek Retractor, f/MatrixMANDIBLE U-shaped, flexible Part Number: 397.232 Multiple lot numbers affected ARTG Number: 153950
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	24/12/2014
Responsible Entity[vii]	Synthes Australia Pty Ltd
Reason / Issue[viii]	The Cheek Retractor for MatrixMANDIBLE U-shaped may not function as intended due to the potential for failure and/or corrosion of the internal spring which has been manufactured from an incorrect material. As an internal part of the instrument, the spring is not in direct contact with the patient. However, in the event that the spring or a subcomponent of the spring was to fail and/or corrode, the theoretical possibility exists that the particles may transfer from the instrument to the patient, potentially leading to an adverse tissue reaction and/or infection. A surgical delay may also arise if the retractor does not work during a procedure and a replacement needs to be found. To date, there have been no reports of adverse events related to this issue.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Customers are asked to inspect invetory and to follow the instructions provided for any affected units. To mitigate risk, should customers with affected instruments require the instrument for emergency cases, please perform a visual and functional inspection, as detailed in the cistomer letter, prior to, during and after use. Customers are asked to exercise caution regarding the risk of corrosion or spring breaking during the procedure.
Contact Information[xi]	1800 796 8437 - Synthes Australia Pty Ltd

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 /

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.