Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-01132-1
Product Name/Description[iii]	50mm Left Standard Ti Mandible Batch numbers: 525190A & 525190B
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	20/10/2014
Responsible Entity[vii]	Biomet Australia Pty Ltd
Reason / Issue[viii]	Biomet Microfixation has initiated this recall following an internal investigation which identified that the Titanium Mandible Implants may exhibit fatigue fracture due to a laser etch that was delivered at a more powerful setting resulting in a wider and deeper etch. The laser is used to etch the part number, lot number, and logo on the implant.
Recall Action[ix]	Hazard Alert
Recall Action Instructions[x]	Biomet Australia is notifying surgeons and hospitals of the potential problem and providing instructions for clinical follow up. Further information can be found on the TGA website.
Contact Information[xi]	02 9878 6100 - Biomet Regulatory Affairs

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.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.