

Recall detail

Type of Product	Medical Device
TGA Recall Reference ⁱⁱ	RC-2016-RN-00091-1
Product Name/Description ⁱⁱⁱ	PyroTitan Humeral Resurfacing Arthroplasty Shapers Multiple Catalogue and Lot Numbers affected ARTG Number: 111050
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	28/01/2016
Responsible Entity ^{vii}	LMT Surgical Pty Ltd
Reason / Issue ^{viii}	It has been determined that certain affected lots of non-conforming product may not be as sharp as intended by design. This may be evident during use by having to increase the applied force to the shaper needed to cut and form the humeral head effectively for the placement of the implant. This increase in force can in-turn, which could create undesirable friction between the shaper and the humeral head that could potentially result in bone tissue being burned.
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Integra LifeSciences is advising users that affected stock can be used if there are no alternatives available. Affected stock will be replaced with unaffected units.
Contact Information ^{xi}	07 3367 6600 - Integra LifeSciences

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