# Recall detail

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|---|---|
| **Type of Product**[i] | Medical Device |
| **TGA Recall Reference**[ii] | RC-2015-RN-00922-1 |
| **Product Name/Description**[iii] | PCA Tapers, LFIT V40 Tapers, V40 Tapers (Vitallium Femoral Heads)<br><br>Multiple catalogue numbers affected<br>Multiple lot numbers affected<br><br>ARTG Numbers: 211858, 211868, 211869 |
| **Recall Action Level**[iv] | Hospital |
| **Recall Action Classification**[v] | Class II |
| **Recall Action Commencement Date**[vi] | 1/10/2015 |
| **Responsible Entity**[vii] | Stryker Australia Pty Ltd |
| **Reason / Issue**[viii] | Stryker has received four customer complaints for LFIT V40 Vitallium femoral heads (manufactured July 7th 2014 – August 15th 2014) reporting that the femoral head could not be assembled with its corresponding V40 stem trunnion at the time of surgery. Upon investigation it was found that the female V40 taper of the four complaint devices were not machined per drawing specifications, leaving a lip protruding from the taper surface at the inner base of the femoral head. This lip prevented the femoral head from successfully locking with the associated male stem trunnion. In each case a new V40 LFIT Vitallium femoral head was opened and used. No other adverse consequences or delays to surgery were reported for any of these complaints. |
| **Recall Action**[ix] | Recall |
| **Recall Action Instructions**[x] | Stryker is advising users to inspect stock and quarantine any affected devices. Stryker will replace any affected devices with unaffected devices. A femoral head that has not achieved a taper lock will be clearly evident during verification, thus reducing the occurrence of the implantation of an unlocked femoral head. |
| **Contact Information**[xi] | 1800 803 601 - Stryker Australia |

## 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