

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2014-RN-00769-1
Product Name/Description ⁱⁱⁱ	Sonopet Console (Ultrasonic Surgical Aspirator System) Catalogue Number: 5450852000 All Serial Numbers ARTG Number: 174364
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	16/07/2014
Responsible Entity ^{vii}	Stryker Australia Pty Ltd
Reason / Issue ^{viii}	Stryker has noticed a trend of complaints regarding insufficient irrigation to the tip of the Sonopet System. Lack of irrigation can potentially lead to excessive heat at the tip. In the case where the irrigation pump fails, saline would not be provided to the tip. As a result the cooling function would be lost and could potentially cause the tip to heat up resulting in tissue burns to the patient.
Recall Action ^{ix}	Recall for Product Correction
Recall Action Instructions ^x	Stryker has updated the Instructions for Use (IFU) for Sonopet to include the following clarifications: <ul style="list-style-type: none"> ·DO NOT use a rigid non-collapsible irrigation container. Failure to comply may cause the flow of irrigation to be drastically reduced and result in overheating of the handpiece tip and/or tip cover. Only use a collapsible irrigation container. ·The irrigation tube must be properly routed through the irrigation pump with the pump cover fully closed and latched. Improper setup of the irrigation tubing may result in an inconsistent or lack of irrigation. ·Provide adequate irrigation to the tip to avoid excessive heat that could result in tissue damage due to unintended contact. <p>Additionally, all existing Sonopet consoles will have an instructional irrigation setup label applied to the side of the console.</p>
Contact Information ^{xi}	1800 803 601 - Stryker Australia

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological