Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2013-RN-01213-1
Product Name/Description[iii]	Vessix Generator System (portable RF generator used with percutaneous angioplasty balloon catheter to deliever low frequency RF energy into the renal artery) Material Number: H749RDNS0100 Catalogue Number: RDNS010 Serial Numbers: 42041, 42020, 42011, 42034, 42042, 42035 ARTG Number: 208743
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	14/11/2013
Responsible Entity[vii]	Boston Scientific Pty Ltd
Reason / Issue[viii]	An investigation has found that the units manufactured since April 2013 were not manufactured according to specification. This manufacturing issue may cause an electrical short in the generator. The issue could result in excessive RF energy being delivered to the renal artery with intermittent temperature spikes that may range between 86 - 93 degrees C.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Customers are requested to segregate the devices immediately and organise for the return to Boston Scientific.
Contact Information[xi]	02 8063 8340 - Boston Scientific Quality Assurance

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.