

## Recall detail

Type of Product <sup>i</sup>	Medical Device
TGA Recall Reference <sup>ii</sup>	RC-2014-RN-00335-1
Product Name/Description <sup>iii</sup>	Teleflex Medical CAPIO Sutures  Catalog Numbers: 833-114, 833-123, 833-124, 833-136, 833-137, 833-213  Lot Numbers: Multiple  ARTG Numbers: 179742 and 164364
Recall Action Level <sup>iv</sup>	Hospital
Recall Action Classification <sup>v</sup>	Class II
Recall Action Commencement Date <sup>vi</sup>	17/03/2014
Responsible Entity <sup>vii</sup>	Boston Scientific Pty Ltd
Reason / Issue <sup>viii</sup>	Boston Scientific has been notified by Teleflex Medical that certain lots of their products did not meet minimum needle attachment strength, knot tensile strength, minimum diameter, or minimum resorption strength requirements. This may result in suture breakage, delay in procedure, wound dehiscence, or the need for additional surgical intervention.
Recall Action <sup>ix</sup>	Recall
Recall Action Instructions <sup>x</sup>	Boston Scientific is recall affected lots of Capio sutures. Distributors are requested to forward the recall letter on to their customers.
Contact Information <sup>xi</sup>	02 8063 8146 - Boston Scientific Quality Administrator

## Footnotes

<sup>i</sup> Type of Product: Medicine, Medical Device, or Biological

<sup>ii</sup> TGA Recall Reference: Unique number given by the TGA

<sup>iii</sup> 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.

<sup>iv</sup> 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.