

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2013-RN-01153-1
Product Name/Description ⁱⁱⁱ	IN.PACT Amphirion Drug-Eluting Balloon (DEB) (used for percutaneous transluminal angioplasty of small peripheral arteries) Supplied in Australia under the Special Access Scheme (SAS)
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class I
Recall Action Commencement Date ^{vi}	8/11/2013
Responsible Entity ^{vii}	Medtronic Australasia Pty Ltd
Reason / Issue ^{viii}	Based on data from clinical study, the IN.PACT Amphirion drug-eluting balloon (DEB) did not meet its safety and efficacy endpoints relative to the percutaneous transluminal angioplasty (PTA) control. The study also identified a potential safety signal given a trend towards an increased rate of major amputations in the DEB study arm. Causality between major amputation and use of the IN.PACT Amphirion DEB could not be established or excluded.
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Medtronic is advising hospitals to quarantine all units of the IN.PACT Amphirion DEB that remain in their inventory.
Contact Information ^{xi}	1800 668 670 - Medtronic Australasia

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 and hospital as appropriate.