

Recall detail

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| Type of Product ⁱ | Medical Device |
| TGA Recall Reference ⁱⁱ | RC-2014-RN-01106-1 |
| Product Name/Description ⁱⁱⁱ | Edwards Lifesciences Vent Catheter Model numbers: E060, E061 & PE062 All Lot Numbers ARTG Number: 144793 |
| Recall Action Level ^{iv} | Hospital |
| Recall Action Classification ^v | Class I |
| Recall Action Commencement Date ^{vi} | 14/10/2014 |
| Responsible Entity ^{vii} | Edwards Lifesciences Pty Ltd |
| Reason / Issue ^{viii} | Edwards Lifesciences has identified a potential patient safety risk which may occur during the use of venting catheters. The malleable stylet which aids during insertion of the vent catheter is coated with a white plastic. The white plastic on the stylet has the potential to become damaged through interaction with the hard plastic suction adapter on the vent catheter. This can result in the disruption of the white plastic coating on the stylet. There is an increased chance of generating particulate if the stylet is withdrawn with sharp bends and/or reinserted into the vent catheter. Reinsertion may lead to an increased potential for particulate to enter the vasculature. |
| Recall Action ^{ix} | Recall for Product Correction |
| Recall Action Instructions ^x | Edwards is adding the following additional warnings to the instruction for use: <ul style="list-style-type: none"> - Do not reinsert the stylet after initial removal. If repositioning of the vent catheter is necessary a new device must be used. - Check the stylet for damage during removal from the vent catheter. If the stylet appears damaged, discontinue retraction and remove the vent catheter and stylet together. - The device is designed and intended for use with suction only. <p>Customers are advised that the customer letter needs to be passed on to all those within their organization to understand the changes that Edwards has made to the instruction for use and contraindication.</p> |
| Contact Information ^{xi} | 1800 222 601 - Edwards Customer Service |

Footnotes

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