



Safety Notice 011/17

Disposable Ventilator Catheter Mounts Failure

29 September 2017

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Chief Health Officer
- Regulatory and Compliance Branch
- Agency for Clinical Innovation
- NSW Ambulance Service

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Medical Services
- Directors of ICU
- Directors of Emergency Departments
- Directors of Operating Theatres
- Directors of Cardiac Services

Expert Reference Group

- Content reviewed by:
- CEC
 - Ministry of Health
 - Agency for Clinical Innovation

Clinical Excellence Commission

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Internet Website:
<http://www.health.nsw.gov.au/sabs>

Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date
September 2018

Background

During a regular quality assurance inspection, Parker Healthcare noticed an irregularity in the expandable tubing of specific tube / mask breathing circuit single-use connectors (Disposable Catheter Mounts).

This was noted across multiple product parts and batches. A Class 2 recall was issued on 11th September 2017 recalling a large number of batches. The link to the recall notice is: <http://apps.tga.gov.au/PROD/SARA/arn-report.aspx>

Current Issue

A faulty item from the same product group, which was not listed in the original recall has been identified at the point of care. This resulted in inadequate ventilation of the patient.

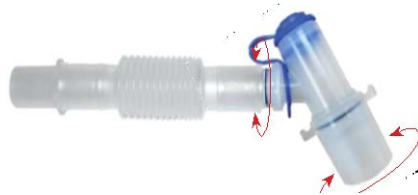
Examination of the disposable catheter mount was found to have no visible hole to enable ventilation.

Upon removal of the catheter mount and reconnection directly to the ventilator tubing, ventilation was immediately restored.

Details of the affected product

Part No. 6000-40[D]/S

Serial No: S-40005 & S-40004



Possible alternate products

Code: 331/5385 – Mount, Catheter, Double swivel elbow, smooth Bore, 150mmLg - Medtronic Australasia which is available on contract. Orders are to be placed directly with the supplier.

If no alternative product is immediately available, direct connection to the patient without a catheter mount is possible while sourcing an alternative product.

Suggested actions to minimise risk

1. Remove any affected stock from circulation.
2. Staff are requested to visually inspect disposable catheter mounts prior to connecting to the patient.
3. Closely monitor patients for adequate ventilation on commencement of ventilation.
4. If inadequate ventilation is detected follow routine processes of assessment to determine the cause.
5. Replace the catheter mount if it is found to be faulty.

Suggested actions by Local Health Districts/Networks

1. Remove any affected stock from circulation.
2. Forward this notice to appropriate area for action.
3. Notify the CEC, product sponsor and TGA if any faulty products are identified.
4. Notify any event into the Incident Information Management System (IIMS).
5. Ensure a system is in place to document actions taken.