Safety Notice 008/21

Medtronic Covidien DAR™ airway products – Deviation in sterilisation processing

29 April 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Regulation & Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Heads of Department
- Directors of Nursing and Midwifery
- Nursing Unit Managers
- Biomedical Engineers
- All clinical departments /services
- NSW Pathology
- Paramedics
- Community& Primary Health Services
- Clinical Product Managers

Expert Reference Group

Content reviewed by:

- HealthShare NSW
- NSW Ambulance
- Agency Clinical Innovation
- Anaesthetic, Intensivist, Paediatric and Neonatology clinicians

Clinical Excellence Commission

Tel: 02 9269 5500

Email: CEC-Recalls@health.nsw.gov.au

Internet Website: http://health.nsw.gov.au/sabs

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

Review date

April 2022

Situation

Therapeutic Goods Administration (TGA) have issued a recall notice and advise that the sterility of some Covidien DAR™ airway products cannot be guaranteed due to quality issues with their sterilisation provider. Medtronic is analysing data to assess whether sterilisation has been achieved despite the deviations in the sterilisation processes. This recently identified quality issue has been present for a number of years. No infection issues have been identified relating to these products.

This issue has the following risks:

- Potential risk of infection from use of affected product
- Supply disruption of alternate product due to increased demand
- Supply disruption whilst Medtronic transfers products to a new sterilisation provider.

NSW Health uses four types of products listed on the TGA recall notice. These include; filters, humidifiers, HMEs, guedels and breathing circuits. The Clinical Product Managers (CPMs) are aware of your specific affected product list and are collaborating with HealthShare to transition to alternate product.

Assessment of risk

The TGA has requested immediate quarantine of all affected products. They have also advised that the goods are aseptically clean and can be used in non-sterile settings. In the event a quarantine may result in the disruption to treatment, users may elect to continue to use these products. Such use would be based on a case-by-case assessment where this is required to ensure the safety of patients and their ongoing treatment, whilst an alternative is identified and made available.

Delaying treatment (surgery or procedure) may cause more harm to the patient. Where possible, use of alternative devices within health services and related networks is advised to ensure that clinical risk to the patient is minimised. If your facility is not in a position to replace any impacted product, but it is necessary to provide treatment using those products, use the impacted product, until an alternative can be sourced. Senior clinician advice should be sought in relation to such decisions where there is a critical shortage, and this should balance the benefits and risks to patients.

Risk Mitigation Strategies

- Undertake a stock review of affected products and available alternative supply by location. Regularly review the status to ensure timely alternate supply is available
- Quarantine affected products where sufficient alternatives are available for use
- Escalate via usual supply chain channels to HealthShare if there are no alternate products available
- Conduct a risk assessment if affected products are required to be used.

Recommended actions required by Local Health Districts/Networks

1. Review the TGA Recall Notice RC-2021-RN-01045-1 and check for affected product
2. Liaise with your CPMs and develop a plan with HealthShare for transition to alternative product
3. If no alternative products are available, you should:
   a) Undertake and document a clinical risk assessment
   b) Follow established local protocols for resource shortage escalation or contingency
   c) Set up systems to ensure that any infections that may be linked to the affected products are reported and monitored.
4. Follow usual governance processes for introduction and use of new products to ensure staff competency before using unfamiliar alternative products
5. Once alternatives are available, remove unused affected stock from shelves and storage areas and quarantine products for later management.

Made Obsolete September 2022
TGA Recall Action Completed