Safety Notice 013/23

Issue date
25 May 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Operating Rooms
- Sterilising Units
- Biomed Engineering Departments
- IPAC Units

Clinicians who may use diathermy

Expert Reference Group

Content reviewed by:
Inter-agency Management Team
Representatives from:
ACI Surgical Services Taskforce
MoH
Biomedical Engineering

Clinical Excellence Commission
Tel: 02 9269 5500
Email:
cec-recalls@health.nsw.gov.au
Internet Website:
https://www.health.nsw.gov.au/sabs/
Intranet Website:
http://internal.health.nsw.gov.au/quality/sabs/

Review date
May 2024

Risk of burn injury from degraded insulated laparoscopic instruments

Situation

Potential safety issues with insulated laparoscopic instruments have been identified after an incident was reported in a patient who had undergone laparoscopic surgery. These instruments include diathermy electrodes, forceps and graspers. On visual inspection of the diathermy electrode used, the insulation material on the electrode had areas which had degraded causing a burn injury to bowel tissue with the patient requiring further surgery. Similar injuries can also result from degraded forceps and graspers used during laparoscopic surgery.

Background

Diathermy is used extensively during open and laparoscopic surgery for dissection and haemostasis. Laparoscopic surgery requires the use of insulated instruments for dissection and diathermy which are passed through a port. Instruments can be reusable or disposable (semi- or fully-disposable). Reusable instruments are subjected to wear and tear from manipulation through the port and at the surgical site, and by cleaning procedures used during reprocessing.

Assessment

There are multiple risks to patient safety from devices which can be mitigated by adhering to operating room guidelines and procedures. Laparoscopic trays including components with insulated instruments which may be used to deliver energy currents should be recorded on an Asset Register to track the model and age of devices for maintenance and retirement. The manufacturers' Instructions for Use (IFU) contain information on reprocessing but often there is no prescribed duration of use which relies on regular visual inspection and electrosurgical safety testing to determine when the device has reached its end of useable life.

Recommendations

- Operating Rooms should:
  - Maintain an Asset Register detailing purchase and maintenance
  - Perform final visual inspection as part of set up
  - Ensure pre- and post-operative instrument integrity checking procedures and documentation
- Sterilising Units re-processing reusable insulated laparoscopic instruments should:
  - Follow the reprocessing procedure detailed in the IFU
  - Perform integrity checks before and after re-processing
  - Record the number of reprocesses per insulated laparoscopic instrument
  - Before sterilisation perform final visual inspection as part of packing
- There should be a system in place whereby routine and as required electrical insulation testing of laparoscopic instruments and cables (from the Electro Surgical Unit to the instrument) takes place.

- The instrument(s) should be replaced when the maximum number of reprocessing events has been reached **or** it fails visual inspection, electrical insulation testing **or** manufacturer's recommended assessment checks.
- Minimise risk of burn injury during diathermy use:
    - Ensure the integrity of the insulation of insulated laparoscopic instruments and integrity of cutting/cauterising/coagulating tip before all procedures
    - Consider single-use diathermy hooks
    - Utilise the lowest effective power setting
    - Minimise time in cutting mode (cutting mode generates higher temperatures than coagulation mode).

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians, clinical departments where diathermy is used.
2. Include this Safety Notice in relevant handovers and safety huddles
3. Undertake a local risk assessment and develop strategies to mitigate the risk of burn injury from diathermy
4. Escalate any concerns to your Clinical Governance Unit
5. Report any incidents associated with these diathermy electrodes into ims+ and TGA.
6. Confirm receipt and distribution of this Safety Notice within 72 hours CEC-Recalls@health.nsw.gov.au