Updated: Risk of burn injury from degraded insulated laparoscopic instruments

SN: 020/25

Issue date:	20 August 2025
Replaces:	Safety Notice 013/23
Content reviewed by:	Representatives from: Agency for Clinical Innovation Surgical Care Network, Ministry of Health, Biomedical Engineering
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	New incidents highlight that routine inspection of insulated laparoscopic instruments may not be consistent. Updated guidance reinforces the need for robust inspection, maintenance, and documentation processes in both Operating Rooms and Sterilising Units to reduce risk of patient harm. Hospitals should consider embedding risk mitigation strategies into local governance documents.
ACTION REQUIRED BY:	Managers and Clinicians
REQUIRED ACTION:	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. Review your local risk assessment and evaluate effectiveness of mitigation strategies to reduce 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.
DEADLINE:	N/A
We recommend you also inform:	Directors, Managers and Staff of: • Operating Rooms • Sterilising Units • Biomed Engineering Departments • IPAC Units • Clinicians who may use diathermy
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	August 2026

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NSW Health

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What has been updated since SN 013/23?

Since the release of Safety Notice 013/23, ten incidents have been reported in ims+, highlighting that routine checks of insulated laparoscopic instruments are not yet consistently implemented across all areas. This updated notice reinforces the need for formalised inspection and maintenance processes in both Operating Rooms and Sterilising Units.

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.

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- 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.
- Implement systems for “routine” and “as required” electrical insulation testing of laparoscopic instruments and cables (from the Electro Surgical Unit to the instrument).
- 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 by:
  - ensuring the integrity of the insulation of insulated laparoscopic instruments and integrity of cutting/cauterising/coagulating tip before all procedures
  - considering single-use diathermy hooks
  - utilising the lowest effective power setting
  - minimising time in cutting mode (cutting mode generates higher temperatures than coagulation mode).
- Consider embedding these recommendations into local governance documents such as policies, procedures, checklists.

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