



# MEDICAL DEVICE CONTROL OFFICE

## Medical Device Advisory Note

Ref: MDAN-2009-01

Issued: 21 August 2009

### DEVICE

Reusable Endoscopic / Laparoscopic instruments and accessories

### PROBLEM

Improper use and aging of endoscopy / laparoscopy instruments and their accessories will lead to device malfunction and failure, which increases the likelihood of patient injury, including unintentional tissue burns at non targeted sites.

### ACTION BY

All staff involved in the use, management or processing of reusable endoscopic /laparoscopic instruments and accessories in a hospital, clinic or day surgery setting.

### ACTION

The above mentioned staff should be aware of the content of this Advisory Note.

### Recommendations

The hospital management should establish policies and guidelines for proper management of reusable endoscopic / laparoscopic devices. These should at least include regular checking of the devices and their accessories, documentation of their use and storage of the devices. The hospital management should obtain from the manufacturer information on the life span of the devices and the recommendations on maintenance. Items having undergone excessive sterilization cycles, showing suspected faults and not in good condition should be removed from use.

#### (1) RECORDS

- (i) To establish a system for tracking the usage of the device. The age and frequency of use should be recorded.
- (ii) To document the number of sterilization cycles undergone by reusable items.  
These records provide the evidence necessary to support a scheduled replacement programme in the future.

- (2) STORAGE
- (i) To carefully store insulated instruments to avoid damage to the insulating mechanism of these products.
  - (ii) To withdraw devices from storage in a controlled manner, i.e. on a first-in-first-out basis.
- (3) INSPECTION AND MAINTENANCE
- (i) To assign competent technical personnel for inspection and maintenance.
  - (ii) To follow the manufacturer's recommendations for testing the devices.
  - (iii) To carry out pre-use testing and routine maintenance of the devices.
  - (iv) To check the insulation function of the devices before and after each procedure.
- (4) OTHER MEASURES TO REDUCE THE RISK OF ELECTROSURGICAL INJURY DURING ENDOSCOPY/LAPAROSCOPY
- (i) To use low-power/low-voltage settings on electrosurgical equipment to minimize the risk of injury from electrosurgical mishaps.
  - (ii) To use leakage current detector / monitor to prevent tissue burns during the electro-surgery. In the event of insulation failure, the electrosurgical unit (ESU) will shut down automatically or trigger an alarm to alert the surgical staff to shut down the system, so that patient injury can be avoided.

#### DISTRIBUTED TO

Healthcare Professionals

#### CONTACTS

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#### FEEDBACK REQUIREMENTS:

None.