衞生署
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DEPARTMENT OF HEALTH
Medical Device Control Office
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本署檔號 OUR REF: L/M(619) to DH/MDCO/20-10/8
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Dear Doctor,

TGA issued safety information on endoscopes repairs

Your attention is drawn to an alert issued by the Therapeutic Goods Administration (TGA) of the Australian Government regarding endoscopes repairs.

The TGA recently reviewed several reported incidents concerning endoscopes repairs which were carried out by non-validated repairers. It is reported that this type of practice has been occurring throughout Australia in both private and public health sectors since at least 1997.

Examples of some poor repair practices with their possible risks include:

Issue	Risk
Non validated lenses replacing the original manufacturer's lenses	Poor image quality, Field of View changed, Poor light output
Non validated spacers replacing original manufacturer's spacers	Poor image quality, Changes the Field of View
Re-etched serial numbers	Difficult to read, method of etching harbours bacteria, instrument cannot be tracked
Missing serial numbers	Unable to track endoscope
Replacement of glass rods in lightpost instead of light fibres	Dull image
Poor welding	Fall apart
Use of adhesive instead of welding	Loosens, Poor sealing of endoscope, moisture absorption
Incorrect distal tip of 70° endoscope	Perforation or abrasion of an organ intra-operatively
Shortened sheath	Sheath becomes visible in image, reducing the field of view
Sharp/abrasive distal tip	Risk of injury to patient and clinical staff
Missing sapphire window	Distal tip prone to scratches, lens likely to crack
Endoscope replaced with incorrect eyepiece ring including engraving	Users will confuse product with another endoscope

In order to minimize the risk, TGA recommends:

1. Healthcare facilities using these type of devices ensure all repairs/maintenance are carried out by the original manufactures of the devices, or
2. Outsourced repairs/maintenances are carried out by technicians trained and validated by the original manufacturer to carry out such practices.
3. Healthcare facilities liaise with sponsors and/or manufacturers of the devices when initiating repair and maintenance program for these types of devices.

4. Healthcare professionals report to the original supplier or manufacturer, any problems associated with the repair and/or maintenance of any medical device.

For details about the alert, please refer to the following link:

http://www.tga.gov.au/hp/iris-articles-2011-110825-scopes.htm

Suspected adverse events related to medical device can be reported to the Medical Device Control Office of the Department of Health. For details, please refer to the website: http://www.mdco.gov.hk under "Reporting Adverse Incidents".

Thank you for your attention.

Yours faithfully,

(Dr Addi Chan)
for Director of Health