

# Medical Device Incident Investigations: Recommendations

## Old and worn sling failure on Haycomp patient lifter

DIR 14102

The TGA recently investigated the reported failure of a sling on a patient lifter. The failure of the sling appears to be related to its age and condition. It was over six years old and was judged by the manufacturer to have had heavy use. All other slings from the same hospital were tested and found to perform in excess of the requirements of ISO/DIS 10535 Hoists for the transfer of disabled persons — requirements and test methods, Section 7.9 'Test methods for body support unit'. All Haycomp slings made since January 2000 have labels attached in accordance with ISO/DIS 10535 and have been factory tested to 1.5 X safe working load (SWL) after 10 washes at 70 degrees C.

The sponsor has issued a customer letter advising of the need for regular inspection of all components of lifting devices, including slings, and the replacement of any damaged components. The TGA endorses this warning and emphasises that the problem is a generic one, not restricted to one manufacturer. Users of patient-lifting devices should regularly inspect all components according to the manufacturer's recommendations. The operating manual for the Joey and Jumbuck lifters, for example, emphasises the need for daily, regular (after 100 hrs) and yearly visual checks and load testing.

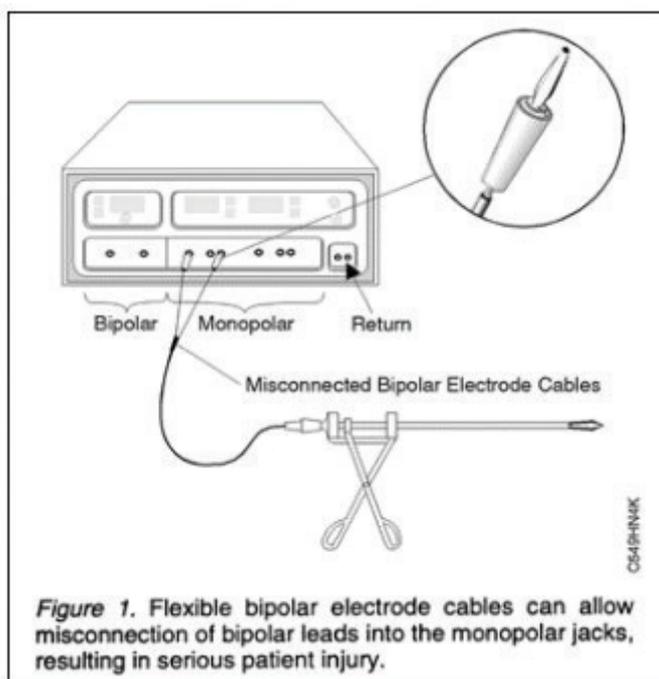
### Recommendation

All manufacturers' instructions should be followed to ensure the safety of lifting equipment including slings. If any component is damaged the whole unit should be withdrawn from service and any faulty part replaced before the device is returned to service.

## Misconnection of electrosurgical bipolar electrodes

The TGA has recently received reports of experienced operating theatre staff misconnecting bipolar electrodes to electrosurgical unit (ESU) monopolar terminals. A literature review has revealed that serious adverse events associated with electrosurgical misconnection have also occurred abroad. The misconnection occurs when the two connectors of the bipolar electrode are accidentally plugged into two of the three monopolar terminals. It appears that this potential for misconnection exists with all brands of electrosurgical bipolar electrodes that have banana-type plugs mounted on flexible cables (see Figure 1).

When misconnected, the bipolar electrode may cause the ESU to inadvertently activate without operator initiation or control. If the monopolar power output has been programmed into the ESU (eg been left at its previous setting), the patient or operator can suffer serious burns or electric shock.



The activation mechanism for the hazardous monopolar current was described by Reeter in 1990: "The closed forceps short-circuit the ESU's switching circuit and turn on the monopolar current."<sup>1</sup> ECRI also published an article on bipolar electrode misconnection in 1993:

*If the bipolar electrode leads are plugged into the active monopolar jack and either one of the monopolar switching jacks, the ESU will be inadvertently activated when the tips of the bipolar forceps either 1) touch and short the leads together or 2) span the tissue with low enough impedance to permit activation.*<sup>2</sup>

Once activated the bipolar electrode will continue to hazardously discharge electricity until the electrode is unplugged or the ESU is turned off. Serious harm may occur during the time taken to deactivate the electrode.

The International Electrotechnical Commission (IEC) parent standard medical electrical device safety requires all patient circuit connections to be designed so that they cannot be hazardously connected to wrong outlets.<sup>3</sup> Similarly, the Australian national parent standard for medical electrical device safety requires the design and construction of bipolar electrodes to prohibit misconnection:

### 56.3 Connections – General

#### a) Construction of connectors

*Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where a SAFETY HAZARD may be caused.*<sup>4</sup>

The TGA intends to approach the Australian ESU suppliers and seek product design changes that will ensure the safety of bipolar electrode connectors in accordance with the IEC60601.1.0 and AS3200.1.0 standards. In the meantime the following recommendations are made for operating theatres.

### Recommendations

1. Alert staff to the hazards of misconnecting the electrosurgical bipolar electrode to the ESU monopolar terminals. The greatest risk is presented to the patient and operator who may be exposed to uncontrolled electrosurgical current at monopolar power levels.
2. Ensure that the bipolar electrode is connected to the proper ESU terminals before operation.
3. Consider using bipolar electrodes that are designed to prevent misconnection.
4. Implement procedures that require the monopolar electrode to be plugged in before the return electrode (eg. thigh pad) is plugged into the ESU.
5. Implement procedures that require all ESU output/operating modes to be set to their minimum until the surgeon is ready to proceed in that mode. An output mode should remain at its minimum setting throughout an operating procedure until that mode is required. If an output mode is no longer required during a procedure it should be set to its minimum output.

### References

1. A.K. Retter, "Bipolar Forceps Misconnection Hazardous" *OR Manager* Feb 1990; 6(2):13.
2. Anonymous, "Misconnection of Bipolar Electrosurgical Electrodes" *Health Devices* Jan 1995; 24(1):34-5.
3. IEC 60601.1.0: 1998 *Medical electrical equipment – Part 1: General requirements for the safety – Parent Standard*. The 'particular' standard does not specifically refer to bipolar electrodes requiring design and construction that prevents misconnection: IEC 60601.2.2: 1999 *Medical electrical equipment – Part 2: Particular requirements for the safety of high-frequency surgical equipment*.
4. AS 3200.1.0: 1998 *Medical electrical equipment – Part 1: General requirements for the safety – Parent Standard*, Clause 56.3 a), p. 89. AS 3200 series is based on the IEC 60601 series.

## Differing alarm mechanisms — arterial oxygen saturation probes

The TGA has been notified of safety concerns with regard to differing alarm mechanisms for arterial oxygen saturation probes utilised by physiological monitoring systems. The TGA would like to bring your attention to the following:

- Physiological monitoring systems may have the capacity to utilise two (2) different types of arterial oxygen saturation probes — either reusable probes or disposable probes.
- The alarm mechanism notifying disconnection of the probe from the patient may differ between the two (2) different probes that may be utilised.
- Users need to be aware of the differing alarm mechanisms to ensure that disconnection does not go unnoticed. The “Operators Manual” for each of the monitoring systems provides details about the differing alarm mechanisms.

Knowledge of any problems that occur, or have occurred, at any time with respect to any of these monitoring systems should be reported to the medical devices Incident Report Investigation Scheme (IRIS) on 02 6232 8695. An IRIS report form can be accessed on the TGA website <www.tga.gov.au>.

## MRI burns and other injuries – learning from experience

A patient received a burn to their arm recently while being scanned in a Magnetic Resonance Imaging (MRI) machine. In this particular report the patient received a burn when their finger touched their side so that the arm formed a loop.

Since MRI machines were introduced in the 1980s there have been numerous reports of patient injury from a wide variety of causes including:

- Injury from flying projectiles pulled toward the magnet bore.
- Metallic implants being moved by the magnetic fields.
- External devices affected by radiation from MRI machine.
- Image artefacts caused by outside signals affect diagnosis.
- Burns from looped leads; iron oxide heating in tattoos or tattooed eyeliner; ECG or pulse oximeter leads conducting currents; and patients contacting the bore of the magnet.

Burns are generally caused by patient contact with an electrically conductive cable, but sometimes they can occur when the tissue of the patient forms an electrically conductive loop, especially when there is a high-resistance point of contact that completes the loop. A concentrated

electrical current or spark can cause tissue damage at the point of contact. The injury resembles burns from other causes. In addition, the use of very high settings on extremities has been known to cause ignition of special cuffs and sleeves.

In rare cases tattoos or tattooed eye liner containing iron oxide pigment has caused minor burns. Patients have also received burns when a limb or other part of the body touched the bore of the magnet. The risk of injury is especially high with unconscious or anaesthetised patients because they cannot report any discomfort.

### Recommendation

Burns from MRI machines can be prevented by ensuring that no electrically conductive loops are formed by cables or by parts of the patient. Limbs should be separated from the body by insulated pillows or foam pads.

Ensure that the patient is not wearing any metal objects, wires that may either move or become hot through induction. Some medical devices are incompatible with MRI. This may not be immediately obvious. For example, the tips of some nasogastric tubes are weighted down by a metal insert.

## Walking frame care and maintenance

The TGA has become aware of a maintenance and care issue with a particular type of rigid walking frame. The walking frames of concern have a plastic tube joint on the rear legs, which is held in place by a screw. When the screw is tightened the plastic joint expands and holds the frame together and provides rigidity. Over time and with use the screws and plastic joints can loosen and, if unchecked, may cause the walking frame to separate.

The frames are used in various settings in the hospital or in the community and are used for long periods of time. The problem described can occur with any frame that is constructed in this manner, but it is also possible that other types of joint may degrade and work loose with age and use. The main message is that even simple devices such as walking frames need some attention and maintenance. Falls, especially among the users of this type of device, can have very serious outcomes.

### Recommendation

Frames should be inspected regularly. If the frames are used in the hospital setting then the engineering department should implement a regular inspection and maintenance schedule, as they would any other medical device. Frames used in the community should ideally be checked every six to twelve months.

Particular attention should be paid to those areas where the stress may be concentrated or there may be high wear. This includes, but is not restricted to, joints, welds, handles, screws or rivets and rubber foot pads.

## MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/10/2003 to 31/12/2003

**Total Number Received: 108**

Cause of Problem <sup>1</sup>		Effect	Result of Investigation	
Biocompatibility	12	Death	TGA News article	1
Component Failure	27	Serious Injury	Company Warned	1
Contamination	4	Temporary Injury	Compliance Testing	2
Design	5	No Injury	No Further Action	46
Electrical	1		Not Investigated <sup>3</sup>	36
Inadequate Instructions	4		Other	3
Labelling	4	<b>Source Category</b>	Problem Not Confirmed	3
Maintenance	4	Medical Administrator	Product Improvement	11
Manufacture	5	Specialist	Recall/Hazard Alert	1
Material/Formulation Deficiency	14	General Practitioner	Refer to GMP	5
Mechanical	8	Coroner	Refer to Surveillance	3
Not Applicable - ADR <sup>2</sup>	2	Nurse	Safety Alert	3
Not Device Related	13	Blood Bank	User Education	4
Other	14	Hospital Supply Service		
Quality Assurance	5	Other		
Unknown	10	Sponsor		
		Overseas Advice		
		Biomed Engineer		

### Notes:

1. The problem causes are not mutually exclusive. For example, a material deficiency may have led to a mechanical malfunction or a biocompatibility problem.
2. ADR stands for Australian Device Regulatory [Action].
3. Every report received by IRIS receives a risk analysis by the Scheme Coordinator and is discussed by a panel of technical and clinical professionals. In the case of reports that are “Not Investigated” the panel has made a decision that further investigation of the particular event is not necessary at that time. However, these reports are logged into the database for future reference and the trend of reports is monitored. In making their decision, the panel considers whether any similar reports have been received previously.