MEDICAL DEVICE SAFETY ALERTS

Angio-Seal Vascular Closure Device

The TGA's Medical Device Incident Report Scheme has become aware of an incident relating to the use of the Angio-Seal Vascular Closure Device where the device was deployed via antegrade puncture of the common femoral artery in a patient who had previous laparoscopic repair of the inguinal hernia using a mesh. The Angio-Seal Vascular Closure Device was used following a digital subtraction angiogram during a peripheral study. The patient became hypotensive following use of the Angio-Seal Vascular Closure Device and further investigation revealed a retroperitoneal haemorrhage, resulting in a blood transfusion. The treating physician noted that the Angio-Seal Vascular Closure Device had become "caught in the mesh from a previous laparoscopic repair of the inguinal hernia".

It should be noted that the surgical mesh probably caused the Angio-Seal device to become entangled. As a result, the Angio-Seal device may not have been fully deployed and this may have contributed to the bleeding.

Please be aware that the Angio-Seal Vascular Closure Device "Instructions for Use" cautions the use of the device where surgical mesh is *in situ*.

Recommendation:

The TGA recommends that devices should be used in accordance with the instructions for use. Good clinical judgement should be used when proceeding with the device under unique conditions, such as use with a surgical mesh, to prevent any patient adverse events.

Risk of injury from the interaction between active/powered implants and diathermy treatment

The TGA has been made aware of the serious injury to two patients overseas who had diathermy treatment which adversely interacted with their active implant, in these cases, neurostimulation implants.

The Medical Devices Agency (MDA) of the United Kingdom has issued a safety notice about this problem.

The problem of nerve or tissue damage could occur if shortwave, microwave or ultrasound diathermy is used on the patient with an active implantable device or leads. This type of therapy is usually referred to as "deep heat". ***This alert does not involve ultrasonic imaging or electrocautery devices.***

Use of diathermy on patients with any active implant can cause heating at the tissue/stimulation electrode interface, which under certain circumstances can result in permanent injury or even death. The exact nature of the tissue or nerve damage depends on the location of the stimulation electrodes implanted in the patient (eg brain, spinal cord, sacral nerve, muscle, cardiac tissue, etc).

Patients affected include those implanted with: deep brain neurostimulators for control of involuntary limb movement, implantable cardiac pacemakers and defibrillators, spinal cord stimulators for pain control, dynamic gracioplasty and sacral nerve stimulators for control of bowel and bladder function, vagal nerve stimulators for epilepsy seizure control, phrenic nerve stimulators and implantable functional electrical stimulators for limb/motor function, cardiomyoplasty cardiac assist device, cochlear implants and patients fitted with implantable drug infusion pumps for control of pain and spasticity, etc. This guidance is already documented on some active implantables instructions for use and also on one brand of IUD, the Multiload cu 375.

In the heating effect described above, it is important to note that permanent damage to nerves and tissue is not caused by a device malfunction. Rather, it is caused by an interaction between the implanted device and the therapeutic diathermy equipment, when both are functioning normally. A risk to patients exists regardless of implant location, diathermy target site, whether the device is on or off and even when a device is removed but the lead electrode remains implanted. Also, the risk of injury still exists if the diathermy device is used to deliver heat or no heat.

What are shortwave diathermy, microwave diathermy and therapeutic ultrasound diathermy treatments?

Diathermy treatments are used by a variety of health care professionals, including physical therapists, nurses, chiropractors, dentists, sports therapists, and others. Health care professionals may refer to diathermy using the term "deep heat" or similar terms. Diathermy means deep heat, but these devices may also be used in a way that causes little or no heating.

Diathermy are treatments that deliver energy to treat specific areas of the body. These treatments are typically used for the following purposes:

- to relieve pain, stiffness and muscle spasms,
- to reduce joint contractures,
- to reduce swelling and pain after surgery,
- to promote wound healing.

Recommendation:

DO NOT use or prescribe shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy for patients with active implants.

1. Physicians should advise patients not to undergo any diathermy treatment.
2. Encourage patients to carry their device identification card at all times.
3. Reinforce to patients that they should declare to practitioners such as physiotherapists, chiropractors, nurses and others that they have an active implant before treatment commences.
4. Professionals are encouraged to ask patients if they have any active implants as part of their initial consultation.
5. This question should be added to any routine patient documentation.
6. If diathermy treatment is considered necessary, advice must be sought prior to treatment from the patient's clinician and/or the manufacturer's representative.
7. Patients with implantable pumps should only have treatment away from the site of the pump. The manufacturer's advice should be sought to obtain the minimum distance of treatment away from the device.

Carbon Monoxide poisoning during Inhalation Anaesthesia

The TGA has become aware of a potential problem of carbon monoxide poisoning for patients receiving inhalation anaesthesia. The problem is caused by an interaction between halogenated volatile anaesthetic agents and the dry sodium or potassium hydroxide found in carbon dioxide absorbents.

This problem has previously been investigated by ECRI (Health Devices Nov 1998; 27(11): 402-4 and Health Devices Nov 2000; 29(11): 435-8).

The reaction occurs when oxygen is left running through the anaesthetic machine for extended periods, for example over the weekend. In most of the reported cases so far this problem has occurred to the first case of the day. The "Soda Lime" or carbon dioxide absorbent becomes dried out so that when halogenated volatile agents flow through the absorbent, carbon monoxide is produced. Carbon Monoxide (CO) binds strongly to haemoglobin forming carboxyhaemoglobin and reduces the red blood cell's ability to carry and release oxygen. Some halogenated agents appear to be more highly reactive than others are. Desflurane, Enflurane and Isoflurane are the agents that have so far been associated with this phenomenon, although this may simply reflect the higher usage of these agents than others.

Detecting this problem can be difficult because carboxyhaemoglobin levels are not monitored during anaesthesia. Therefore CO exposure may remain undetected until the patient shows unexpected signs of respiratory distress and confusion or coma. CO exposure may not at first be considered and until fresh blood samples are analysed for CO the diagnosis of the problem may not be made until much later.

Recommendations:

Carbon Monoxide poisoning usually only happens when certain conditions occur: anaesthetic machine left turned on, oxygen flowing through even at low flow rates and the machine being left in this condition for an extended period of time.

To protect against this type of problem happening it is recommended that:

- Anaesthetic machines be switched off at the end of the day's use,
- Operations check at the beginning of the day that the machine has been turned off. If this has not happened, the machine should be turned off and the carbon dioxide absorbent replaced.

MEDICAL DEVICE INCIDENT REPORTING AND INVESTIGATION SCHEME STATISTICS REPORT
Device Incident Reports 01/04/2001 to 30/06/2001

Number received: 138

Cause of Problem	
Biocompatibility	8
Component failure	25
Contamination	1
Design	5
Diagnostic Inaccuracy	1
Electrical	8
Inadequate Instructions	3
Labelling	2
Maintenance	1
Manufacture	14
Material/Formulation Deficiency	19
Mechanical	6
Not Device Related	25
Other	16
Packaging/Sterility	2
Quality Assurance	4
Unknown	29

Effect	
Death	4
No Injury	92
Serious Injury	14
Temporary Injury	28

Result of Investigation	
Bulletin Article	2
Company Warning	2
Compliance Testing	4
No Further Action	43
Not Investigated	70
Other	5
Problem Not Confirmed	9
Product Improvement	7
Recall/Hazard Alert	5
Refer to GMP	1
Refer to Surveillance	1
User Education	4

Source Category	
Medical Administrator	6
Specialist	13
Coroner	3
TGA	1
Nurse	24
Blood Bank	13
Hospital Supply Service	16
Other	7
Patient/User	2
Sponsor	44
Overseas Advice	1
Biomed Engineer	8