NSW HEALTH

Safety Notice

SN:003

October 2006

Action required by:

- Directors of Clinical Operations

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

We recommend you also inform:

- Directors of Medical Imaging
- Renal physicians
- Directors of Surgical Services
- Directors of Nursing

For further information:

Please contact BIOTRONIK Australia Pty Ltd on

02 9497 3700 or enquiry@biotronik.com.au for further information on Peiron stents.

Quality and Safety Branch
NSW Department of Health
Tel. 02 9391 9200
Fax. 02 9391 9556
Email
quality@doh.health.nsw.gov.au

www.health.nsw.gov.au/quality/sabs/register.html

Peiron Stent in renal arteries

Peiron Stent fracture in renal arteries

The Peiron balloon mounted stent (a product of BIOTRONIK Australia Pty Ltd) is used in the treatment of atherosclerotic disease.

There have been five reports of Peiron stent fracture following use in the renal artery between 2003 and 2005. All five resulted in adverse outcomes including loss of the kidney and one of these occurred in Australia. In 2006, two additional reports of partial stent fractures were identified in NSW, with neither patient suffering an adverse outcome.

In-house testing conducted by BIOTRONIK Australia Pty Ltd revealed that the mobility of the renal artery increased the risk of stent fracture with four reports identifying the stent fracture occurring at 7, 13, 14 days and 6 months post implant.

There is no clinical data to determine the risk level and the incidence of fracture. The time point of fracture depends on the forces that cause the stent to break and this will vary from patient to patient.

Action taken following notification to NSW Health

- In 2005, a fracture of a Peiron stent in a renal artery was notified to NSW Health. Further investigation identified that the indications for use of the Peiron stent had been changed to specifically exclude the use of the stent in renal arteries.
- In light of this information, in October 2005, NSW Health alerted all Chief Executives and Directors of Clinical Governance Units that Peiron stents were **not to be used in renal arteries** and that each health service was to identify the cohort of patients that had Peiron stents inserted.
- In November 2005 at the request of the Therapeutic Goods Administration (TGA), BIOTRONIK Australia Pty Ltd issued a Safety Alert advising of the changed indications for use.
- A patient information and management package was developed and used by relevant Area Health Services in the management of potentially affected patients in November 2005. All affected patients have been notified.
- As a consequence NSW Health issued the Lookback Policy Directive PD 2006_070 in August 2006 for mandatory compliance by Area Health Services.

Conclusion

Area Health Services should ensure that Peiron stents are **NOT used for renal artery stenting**.

Action Suggested for Area Health Services

1. Determine if this Notice is relevant for your Area Health Service
2. Ensure that this Safety Notice is distributed to all relevant stakeholders
3. Ensure policies and protocols are updated to include this information
4. Ensure that staff follow the manufacturers instructions.