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SAFETY AUTHORITY
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THE MINISTRY OF HEALTH
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7 May 2009

Mr Jim Turner
RANZCOG New Zealand Committee
Level 3 – Navigate House
69 Boulcott Street
PO Box 10611
Wellington

Dear Mr Turner,

Surgical Mesh Incidents Reported to Medsafe

Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, has investigated a number of reports it has received regarding complications involving surgical mesh devices used in the treatment of pelvic organ prolapse. It has concluded that when used in accordance with the manufacturer's directions for use (DFU) by appropriately trained surgeons that these devices do not present an unreasonable safety risk to patients. Surgeons implanting surgical mesh devices are recommended to follow the manufacturer's DFU and the guidance published by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) in July 2007.

Background

Medsafe has received a number of adverse event reports relating to post implantation complications associated with the use of surgical mesh devices for the treatment of pelvic organ prolapse and stress incontinence. During the investigation of these incidents Medsafe received input from the Accident Compensation Corporation (ACC) and consulted with the RANZCOG, the Australian Therapeutic Goods Administration (TGA), the Medical Device Incident Review Committee (MDIRC, an independent committee of representatives from healthcare professional colleges administered by the TGA and constituted to review medical device incident reports) and suppliers of surgical mesh products.

Key points noted from the investigation are summarised as;

- The popularity of surgical mesh for treatment of pelvic organ prolapse and stress incontinence has greatly increased over the past decade
- There have been many changes in the equipment and techniques used with surgical mesh products since the first devices were introduced
- Female pelvic organ prolapse and stress incontinence are difficult conditions to treat

Medsafe Conclusions

The Director-General of Health may only take action if a medical device is believed to be unsafe (refer Section 38 of the Medicines Act 1981). When used in accordance with the manufacturer's DFU by appropriately trained surgeons Medsafe has concluded that surgical mesh devices do not present an unreasonable safety risk to patients. As the Medicines Act 1981 does not require the effectiveness of a medical device to be evaluated prior to its supply in New Zealand no determination has been made of the effectiveness of these devices.

The MDIRC committee agreed there appeared to be a training issue and recommended that an appropriate training program be put in place by the manufacturers in cooperation with professional organisations such as the RANCOG to manage problems.

Medsafe supports the guidance provided by RANZCOG in College Statement C-Gyn 20 "The Use of Mesh in Gynaecological Surgery", dated July 2007, which states

> *Mesh should only be used by Specialist gynaecological surgeons who have participated in a quality based training program and have been trained in the relevant surgical technique.*
> *Fellows should be familiar with the relevant published literature on best practice, before using mesh in gynaecological surgery, as there are potential major complications in the use of mesh in the management of pelvic organ prolapse. There should be a documented consent process.*
> *Patients should be counselled on alternatives such as native tissue repair.*

Medsafe notes that the above College Statement is due for review in July 2009. Please advise Medsafe of the outcome of this review. If the statement of the College's position changes subsequent to the review please provide a copy of the revised document to Medsafe for our records.

Medsafe has now closed its files on the events reported to date, but will continue to investigate new events when they are reported. Data on all reported events may be used to monitor for trends.

For further information about this matter please contact Robert Jelas, Senior Advisor Medical Devices (Post Market) at (04) 819-6881 or via email at robert_jelas@moh.govt.nz.

Yours sincerely,

Robert Jelas
Senior Advisor Medical Devices (Post Market)