11th November 2009

[redacted]
Acting IRIS Coordinator
Incident Report and Investigation Scheme
Market Vigilance and Monitoring Section
Therapeutic Goods Administration
Post Office Box 100
WODEN ACT 2606

Dear [redacted],

I must apologise for the delay in preparing this report. It has taken me several weeks to get myself organised having recently been on holidays.

I have enclosed copies of the relevant slides from my presentation to the Royal Australian College of Obstetricians and Gynaecologists.

The presentation I delivered, related to the first 71 cases of mesh complications we have dealt with. This number however has now exceeded over 100 and as yet we have not analysed fully the data relating to these complications.

In this presentation mesh complications relate to all implanted mesh and also to the new tissue anchors which have been introduced to secure mesh to the uterosacral ligaments and other structures at the time of vaginal repair.

You will see from this report that mesh complications can sometimes be irreversible, with pain and dysfunction long term for the patient. Multiple surgical approaches are required to remove mesh and tissue anchors, as they are not easily identified on imaging or clinical examination. The only meshes easily identified by specialist ultrasonographers are the mid-urethral slings for the management of stress incontinence of urine. Tissue anchors are particularly difficult to identify as they do not always sit where originally placed and can migrate to other areas of the pelvis.

To date we now have 5 very significant complications associated with the placement of tissue anchors. Several of the patients we have removed tissue anchors from have required multiple surgical procedures and have been left with deep seated pelvic pain. The most frequently used prosthesis in vaginal surgery are:

1. Anterior, posterior and total Prolift grafts manufactured by Johnson and Johnson.

2. Apogee and Perigee devices manufactured by American Medical Systems

3. Tissue anchors called Tissue Fixation Systems manufactured by TFS Manufacturing Pty Ltd.

...2.

The Urogynaecology Clinic at King Edward Hospital and the private urogynaecologists in Western Australia are concerned with the increasing mesh complications we are seeing. The patients are being subjected to multiple surgical procedures because of the difficulty in locating the tissue prosthesis in the vagina and also are being left frequently with long term irreversible side-effects from the prosthesis inserted.

I am not advocating the withdrawal of vaginal prosthesis for prolapse and incontinence surgery. I am suggesting that implanted devices should be made more easily identifiable in the vaginal tissues by both clinical and imaging techniques.

Yours sincerely,

J.T. JEFFERY

Enc Slides

c.c. Dr N Tsokos, Department of Urology, King Edward Hospital, Bagot Road
Subiaco WA 6008
Enc. Slides

History of vaginal mesh in WA

- 1990s Integral theory: Ulmstein and Petros
- IVS introduced in WA 1990s
- TVT introduced in WA Sep 1999
- SPARC
- Gynaemesh April 2003
- Obturator slings (TVTO August 2005, Monarc)
- Prolapse repair: Prolift Aug 2005(Ant, Post, Total), Apogee and Perigee,
- Tissue anchors

Mesh removal in WA

- Case series
- Dedicated Urogynaecological unit
- Combined with private practice of the same surgeons
- Cases referred in from all over the state

Mesh removal in WA

- 71 cases (but now over 100)
- 20-88 years (mean 60yrs)
- 20 cases from KEMH
- 50 from private rooms

Reasons for removal

Mesh erosion	37	52%
Dysfunctional voiding	12	17%
Chronic Pelvic Pain	4	5.6%
Dyspareunia	1	1.4%
Abscess (pelvic)	3	4.2%
Abscess (buttock)	1	1.4%
Tissue anchor erosions	1	1.4%

Reasons for removal

ME, DV, Dyspareunia	1	1.4%
ME, Dysfunctional voiding	1	1.4%
Dysfunctional voiding and Pelvic Pain	7	9.8%
Altered clitoral sensation, Dyspareunia, UTIs	1	1.4%
Enlarging diverticulae, Pelvic Pain, DV	2	2.8%

Types of mesh – mid urethral sling

TVT	15	21%
TVTO	1	1.4%
IVS	10	14%
SPARC	7	9.8%
Atrium	2	2.8%
Teflon/Nylon	4	5.6%
Mesh with tissue anchors	1	1.4%

ME

Types of Mesh - Prolapse

Gynaecare Mesh (Ant, post or both)	3	4.2%
Ant Prolift	5	7.0%
Post Prolift	4	5.6%
Total Prolift	4	5.6%
Perigee	1	1.4%

Type of Mesh – combined procedures

Combined procedures: –Atrium Mesh and TVT –Total Prolift and TVT –Total Prolift and TVTO –Perigee and TVTO –TVT and Pelvicol	5	7%
Unknown	9	12.6%
TOTAL	71	100%

Timing of complications

- Range 1-82 months
- Subset Analysis
  - TVT, TVTO, SPARC, Ant and Post Prolift, Perigee (12 months)
  - IVS, Nylon, Atrium, Unknown – significantly longer time to removal (48.9 months)

Repeat procedures:

- Further erosions: 14 (19.7%)
- Repeat operations:17 (23.9%)
- Number of repeat procedures: 1-6
- Types of ops:
  - Repeat vaginal mesh excisions
  - Further removal of tape
  - Urethral dilatations
  - Urethrolysis
  - Division of levator ani
  - Intravesical and intraperineal Botox

- Multiple procedures are required because the mesh is often difficult to locate surgically and meshes are not able to be identified using imaging unless a very skilled operator uses ultrasound for mid urethral slings.
- Not for other TVM
- Not all meshes are coloured

Long term outcomes: 12 month FU

Improved / resolved	32	45%
Further ops	16	22%
Recurrent SUI	4	5.6%
Ongoing Voiding dysfunction	3	4.2%
Ongoing Pain	4	5.6%
LTFU	5	7%
Pending	7	9.9%

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Letter 22/01/2010

Dr Tim Jeffery
Obstetrician, Gynaecologist,
Urogynaecologist
[redacted]

Dear Dr Jeffery,

Re: Concerns related to urogynaecological surgical mesh

Thank you for your report to the TGA dated 11 November 2009, relating your concerns with urogynaecological surgical meshes.

The Market Vigilance Monitoring Section of the TGA is currently undertaking a product review of this range of surgical meshes. To assist the TGA to better target this review could you please provide responses to the following:

1. You noted the prostheses most frequently used in vaginal surgery as products supplied by Johnson & Johnson, American Medical Systems and Tissue Fixation Systems. Are the concerns you have raised related to the products only from these sponsors?
2. The TGA, with your permission would like to send selected parts of your presentation in a letter to these three sponsors to elicit more focused responses to the issues you have raised. We will remove the "Types of Mesh" slides as this information may be commercially sensitive to the sponsors.
3. If you give your permission to include this information in a letter to those sponsors would you prefer the information source remain anonymous or identified as being received from you as presented at the Australian College of Obstetricians and Gynaecologists conference?
4. Could you please provide a time period for the 71 incidents quoted?
5. Do you know whether any of these problems / complications have been reported to the sponsor/s and/or the TGA? If so, can you please provide some details of such reports?
6. Do you have any further comments to the TGA that may be of value when addressing this issue with the sponsors of the devices?

The TGA encourages reporting to the TGA Incident Report Investigation Scheme (IRIS - http://www.tga.gov.au/problem/devices.htm) any further incidents related to these types of devices. These reports can assist the TGA to monitor the performance and safety of such devices and if necessary, take regulatory action.

Your timely response to this request for information would be appreciated.

Please send the information marked to my attention via email at [redacted] or via post to;

30 January 2010

[redacted]
Market Vigilance Monitoring Section
Office Devices Blood Tissues
Department of Health & Aging
Therapeutic Goods Administration
Post Office Box 100
WODEN ACT 2606

Dear [redacted],

Thank you for your continued interest in our concerns regarding mesh.

Your recent letter dated the 22nd January, asks several questions. With reference to your letter, I will answer your specific points.

1. The prosthesis we are most frequently associated with are supplied by Johnson & Johnson, American Medical Systems and Tissue Fixation Systems. There are however increasing numbers of meshes for insertion in the vagina being made available on the market. It is my understanding that none of these mesh products includes any significant means of identifying the mesh in the tissue either clinically or radiologically.

2. I am happy for the TGA to send as much of my presentation to the sponsors as you think necessary. This presentation was made at an open meeting of the regional branch of the Royal Australian College of Obstetricians and Gynaecologists. The mesh sponsors were present in the audience at the time of the presentation.

3. As the sponsors were present at the presentation, I have no problems with the information being sent out under my name or whatever reference the Department thinks is appropriate.

4. It is difficult to give a specific time for the mesh complications. The complications date from the time the mesh was first used in Western Australia.

5. As far as I am aware, none of the mesh complications in the series presented, or since, have been reported to the TGA by either the surgeons involved or the sponsors of the mesh used.

...2.

6. The use of mesh in the management of vaginal prolapse is of significant concern. The sponsors are pushing the use of mesh for all prolapse repairs. Urogynaecologists, the American College of Gynaecologists and the Royal Australian College of Obstetrians and Gynaecologists suggest that mesh should only be approved for recurrent prolapse repairs. Primary surgery has a success rate of approximately 60% with an anterior repair and significantly higher with a posterior vaginal repair. It is difficult to understand with such statistics why mesh is being used so freely by generalist gynaecologists in the management of primary vaginal prolapse surgery.

I am happy to continue liaising with you regarding the role of mesh, as the urogynaecologists in Western Australia are significantly concerned about the complications we are seeing with the free use of mesh in vaginal surgery.

Yours sincerely,

J.T. JEFFERY

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

DR J.T Jeffery
King Edward Hospital
[redacted]

Dear DR Jeffery

DEVICE INCIDENT REPORT DIR 20155 - mesh/

We have now completed our evaluation of the incident you reported to the Therapeutic Goods Administration concerning the above device.

A copy of the Incident Report Investigation Scheme (IRIS) database entry, complete with closing recommendations is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please do not hesitate to contact me here in Canberra on [redacted]

Yours sincerely

[redacted]

[redacted]

Incident Report and Investigation Scheme
Market Vigilance and Monitoring Section
Therapeutic Goods Administration

16/11/2009

DIR/20155 mesh/

Reporter#

Exempt/Not on Artg: Y
Device: Mesh
Model No:
Batch No:
Serial No:

Description: I previously wrote to the FDC regarding difficulties we have in localising implanted mesh and prothesis in the vagina, in view of the inability to image the implanted device. We are seeing increasing numbers of mesh complications. The new anchor bone system is also leading to significant problems with pain and discharge. Localising the mesh and implanting devices is extremely difficult without the aid of imaging.
Many women are experiencing long term irreversible problems associated with implanted mesh ands securing devices in the vagina and this is going to become an increasing and difficult problem for surgeons tackling removal of these implanted devices.

Recommendation:
This prooduct has been referred for post market review of the concerns stated within this report. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Dates
Received: 21/09/2009
Entered: 21/09/2009
Completed: 16/11/2009

***** End of DIR/ 20155 *****

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

DR Jeffery
King Edward Hospital
[redacted]

Dear DR Jeffery

DEVICE INCIDENT REPORT DIR 20155 - mesh/

The information in your compliant letter to Dr Bruce McPhee regarding the imaging of implanted prosthesis was forwarded onto the Therapeutic Goods Administration (TGA) for further investigation.

The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia and New Zealand, through voluntary cooperation between medical device users, industry and government.

While suppliers and/or manufacturers are responsible for their products, the Scheme can play an important role in ensuring effective and efficient resolution or prevention of incidents.

In addition to reporting safety issues, everyone is encouraged to report any issues of the quality and efficacy of medical devices. Such examples include compromised sterility, packaging or labelling defects and poor construction or design.

However without specific information about the device (name/model of device, clinic name/location) an investigation would difficult. I have been unable to clearly identify the new bone anchor system you mentioned in your letter to Dr McPhee

Could you please provide more information to assist with this initial stage of our review of this device. This information should include but is not limited to

1) Brand/Trade name

2) Manufactures/Suppliers name & contact

The information you provide will be added into the Therapeutic Device Incident Reporting Database, where it will be evaluated against any previous incidents with the same or similar devices. We will also contact the product sponsor requesting details of any similar reports.

If you wish to remain confidential in this matter please indicate this in your reply

This process may take some time, but be assured we will advise you of the final outcome of our investigations. However, should you have any queries in the meantime, please do not hesitate to contact me on [redacted]

Thank you for your participation in the Medical Device Incident Report Investigation Scheme.

Yours sincerely

[redacted]

[redacted]
Acting IRIS Coordinator
Incident Report and Investigation Scheme
Market Vigilance and Monitoring Section
Therapeutic Goods Administration

21/09/2009

Therapeutic Goods Administration
Device Incident Reports
Report to Sponsor

DIR / 20155 mesh/

Exempt/Not on Artg: Y

Device: Mesh

Model No: Batch No: Serial No:

Reporter Details: Confidential: No

DR J.T Jerrery

Position: Urogynaecologist

Institution: King Edward Hospital

[redacted] AUST

Phone: [redacted]

Incident Description: I previously wrote to the PDC regarding difficulties we have in localising implanted mesh and prothesis in the vagina, in view of the inability to image the implanted device.
We are seeing increasing numbers of mesh complications. The new anchor bone system is also leading to significant problems with pain and discharge. Localising the mesh and implanting devices is extremely difficult without the aid of imaging.
Many women are experiencing long term irreversible problems associated with implanted mesh ands securing devices in the vagina and this is going to become an increasing and difficult problem for surgeons tackling removal of these implanted devices.

Date Received: 21/09/2009

***** End Of DIR / 20155 *****

15th July 2009

Dr Bruce McPhee
The Chairperson Prosthesis Committee
GPO Box 9848
CANBERRA ACT 2601

Dear Dr McPhee,

RE: **IMAGING OF IMPLANTED PROSTHESIS**

I previously wrote to the Committee regarding the difficulties we have in localising implanted mesh and prosthesis in the vagina, in view of the inability to image the implanted device.

We are seeing increasing numbers of mesh complications. The new bone anchor system is also leading to significant problems with pain and discharge. Localising the mesh and implanting devices is extremely difficult without the aid of imaging.

In September 2009, I have been asked to present mesh complications to the Royal Australian College of Obstetricians and Gynaecologists. As I have written to the Prosthesis Committee in the past regarding imaging of implanted devices, I would like to present your decision on the need for enabling imaging of the implanted vaginal devices.

Many women are experiencing long term irreversible problems associated with implanted mesh and securing devices in the vagina and this is going to become an increasing and difficult problem for surgeons tackling removal of these implanted devices.

Yours sincerely,

J.T. JEFFERY

Urogynaecologist
Urogynaecologist to the Urology Clinic at King Edward Hospital
Gynaecological Representative on the Cases Committee of the MDA National

Cc: Chairman, The Chair of the Urogenital Prostheses Clinical Advisory Group

Australian Government

PDC

Prostheses and Devices Committee

Dr Tim Jeffery
[redacted]

Dear Dr Jeffery

Re: Mesh Product Safety Concerns – Prostheses Devices

I refer to your recent correspondence that highlights the difficulties in localising implanted mesh and prosthesis due to the inability to image the implanted device and the resulting complications often associated with these procedures.

The PDC has considered the clinical safety concerns raised and agree that all mesh prostheses products should include a radiological marker to improve surgical outcomes and decrease the rate of complications due to the inability of imaging these devices.

The PDC also sought advice from their expert clinical advisory group who suggested that it would be additionally beneficial to have the mesh distinctively coloured so it is more visible intra operatively.

The PDC has subsequently written to the TGA with a recommendation that its Medical Devices Evaluation Committee consider that the presence of a radiological marker and colour change be reviewed to ensure compliance by the sponsors of these products. I have also forwarded your concerns to Medical Services Advisory Committee (MSAC) to consider the issue of clinical safety.

In your letter you advise that you will be presenting on mesh complications to the Royal Australian College of Obstetricians and Gynaecologists in September. The PDC would be interested to receive a copy of this paper to provide to the TGA and MSAC to inform their deliberations.

Thank you for bringing this matter to the PDC's attention. I will let you know the outcomes of any decision by the TGA and MSAC.

Yours sincerely

[redacted]

Dr David Hale
Acting Chair
Prostheses and Devices Committee
15 September 2009

Secretariat:
Department of Health and Ageing
Private Health Insurance Branch (MDP86)
GPO Box 9848
CANBERRA ACT 2601

Phone: (02) 6289 6979
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Email: prostheses@health.gov.au