MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Adverse Event Reports Relating to Surgical Mesh Implants

Summary of reports received by Medsafe

April 2015

MINISTRY OF HEALTH
MANATU HAUORA

New Zealand Government

Document History

Revision Date	Version Number	Summary of Changes
0	Dec-2013	Reports received by Dec-2013
1	Mar-2014	Addition of reports received to Mar-2014
2	Sep-2014	Addition of reports received to Jun-2014
3	Apr-2015	Document history information added Addition of reports received to Dec-2014 Gynaecological mesh reports divided into separate tables for Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP) devices Summary of reports received added Summary of devices supplied in New Zealand added

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About Medsafe

- Medsafe is the New Zealand Medicines and Medical Devices Safety Authority and is responsible for the regulation of therapeutic products in New Zealand through administration of the *Medicines Act 1981*.
- Medsafe is a business unit of the New Zealand Ministry of Health.
- Medsafe's Mission is: 'To enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit.'
- In working to achieve the stated mission Medsafe:
  - applies accepted international practice to the regulation of therapeutic products
  - provides efficient services measured against agreed stated performance indicators
  - prepares and maintains regulatory guidelines reflecting sound science and promoting evidence based decisions
  - applies processes that are consistent, transparent and minimise the costs of regulatory action
  - provides timely and unbiased information to health professionals and consumers about the safe use of therapeutic products.

Introduction

Concerns have been raised by overseas regulators about the implantation of surgical mesh devices for the treatment of pelvic organ prolapse, stress incontinence, and hernia repair. Medsafe has been monitoring adverse events relating to surgical mesh devices and has made a commitment to making a summary of these reports available to the public. The first report was published in August 2013.

For some reports, information has not been available or obtainable.

For further information about surgical mesh devices please refer to the information published on the Medsafe website at the link below:
http://www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp

Report Period

This report covers adverse event reports received by Medsafe from 2005 until 31 December 2014.

Key to data tables

The table below explains the information contained in this summary.

Guide to table Field	Explanation
Event Date	Date the device was originally implanted in the patient
Report Date	Date the report was received by Medsafe
Adverse Event	Generalised information on the injury/harm reported
Brand	Brand of the device reported to have been used
Device	Model name or family of product reported to have been used
Model	Manufacturer's model number/order code of device (where known)
Batch	Manufacturer's batch/lot number of device (where known)
Sponsor	The New Zealand supplier of the device
Medsafe Reference	Record number of the report in the Medsafe post market investigation database

Summary of Reports

Since 2005 Medsafe has received a total of 76 adverse event reports relating to surgical mesh and stress urinary incontinence devices. By product types the numbers of reports received are:

Stress Urinary Incontinence devices	23
Surgical Mesh (Pelvic Organ Prolapse, POP)	47
Surgical Mesh (hernia)	7
	77

These reports have been received from a range of reporters as summarised below:

Suppliers of devices (sponsors)	26
Healthcare professionals	2
Accident Compensation Corporation (ACC)	32
Patients	17
	77

To better understand the rate of incidents being reported Medsafe requested information about the quantity of devices supplied in New Zealand between 2005 and October 2014. The information supplied by the importers of these devices in New Zealand is summarised in the table on the next page. (Note that these figures relate to the number of devices supplied in New Zealand and not the number of devices implanted.)

Summary of devices supplied in New Zealand for the period 1 Jan 2005 to 31 October 2014

Product Grouping	2005 (units)	2006 (units)	2007 (units)	2008 (units)	2009 (units)	2010 (units)	2011 (units)	2012 (units)	2013 (units)	2014 (units)	Total Units
Stress Urinary Incontinence Devices	1314	1533	1721	1625	1844	1833	1761	1924	2131	1408	**17094**
Pelvic Organ Prolapse Devices	557	591	568	842	1011	755	679	597	377	220	**6197**
Hernia	3756	4212	3460	2780	2661	2467	2805	3860	3911	2984	**32896**

Summary of adverse event reports received by Medsafe by year report received for the period 1 Jan 2005 to 30 September 2014

Product Grouping	2005 (reports)	2006 (reports)	2007 (reports)	2008 (reports)	2009 (reports)	2010 (reports)	2011 (reports)	2012 (reports)	2013 (reports)	2014 (reports)	Total Reports
Stress Urinary Incontinence Devices	-	-	-	6	3	-	2	-	7	5	**23**
Pelvic Organ Prolapse Devices	-	1	1	9	1	1	2	2	20	10	**47**
Hernia Devices	-	-	-	-	1	1	3	1	1	-	**7**

Reports - Stress Urinary Incontinence (SUI) Devices

Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
1-Jan-05	16-Sep-08	Urinary tract infections & vaginal bleeding	Ethicon	TVT Prolene	Unknown	Unknown	Johnson & Johnson Medical NZ	6607
1-Jan-05	3-Feb-09	Infection	Tyco	IVS Tunneller	Unknown	Unknown	Covidien	7036
30-Oct-05	15-Apr-08	Rectal damage/injury/tear	American Medical Systems	SPARC Sling	72403657	375289008	Obex	6111
7-Jun-06	15-May-14	Erosion of mesh into vagina	Tyco	IVS Tape	Unknown	Unknown	Covidien	16438
5-Jul-06	15-Apr-08	Vaginal damage/injury/tear	Ethicon	Gynaecare TVT	810041B	1319566	Johnson & Johnson Medical NZ	6111
19-Jul-06	15-Apr-08	Procedural complications	Ethicon	Gynaecare TVT	810081	2906367	Johnson & Johnson Medical NZ	6111
7-Sep-06	20-Mar-13	Pain & incontinence	Covidien	IVS Tunneller	IVS-02	04H-109	Covidien	14391

Medsafe uses adverse event reports to monitor the safety of medical devices. This is part of the on-going monitoring and compliance activities undertaken by Medsafe. An adverse event report does not mean that the medical device is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible.

Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
11-Oct-07	15-Apr-08	Vaginal damage/injury/tear	Textile Hi-Tech (THT) Bio-Science (incorrectly recorded as Labastide Rouairoux previously)	Swing System	Unknown	5042904	Surgical Supplies	6111
6-Jan-08	11-Jul-11	Infection	American Medical Systems	Monarc Sub Fascial Hammock	Unknown	Unknown	Obex	10926
4-Apr-08	15-Apr-08	Vaginal damage/injury/tear	Ethicon	TVT Prolene	810081	1307149	Johnson & Johnson Medical NZ	6111
2-Sep-08	28-Sep-11	Perforation of Bladder	Ethicon	Gynaecare TVT	810041B	1207535	Johnson & Johnson Medical NZ	11276
27-Nov-08	12-Jun-13	Erosion	American Medical Systems	AdVance Transorburator Sling	Unknown	Unknown	Obex	14817
28-Nov-08	20-Sep-13	On-going pain and mesh erosion	Ethicon	TVT Obturator System	810081	Unknown	Johnson & Johnson Medical NZ	15406
2-Dec-08	20-Mar-09	Infection	Ethicon	Ethicon TVT Obturator	810081	Unknown	Johnson & Johnson Medical NZ	7224

Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
18-Dec-08	26-Sep-13	On-going pain and mesh erosion	Ethicon	TVT Obturator System	810081	Unknown	Johnson & Johnson Medical NZ	15442
4-Apr-09	11-Feb-13	Pain & urinary retention	American Medical Systems	SPARC Sling	Unknown	Unknown	Obex	14192
24-Jun-09	28-Jul-09	Pain	Ethicon	Ethicon TVT Obturator	810081	Unknown	Johnson & Johnson Medical NZ	7692
2-Aug-10	20-Aug-13	Patient experienced unknown injury	Boston Scientific	Obtryx	Unknown	Unknown	Boston Scientific	15273
18-Nov-10	15-May-14	Erosion of mesh into vagina	Ethicon	TVT tape	Unknown	Unknown	Johnson & Johnson Medical NZ	16439
1-Jan-12	13-Mar-13	Erosion	Ethicon	Gynaecare TVT	810081	Unknown	Johnson & Johnson Medical NZ	14357
Unknown	2-May-14	On-going leg and vaginal pain	American Medical Systems	Monarc Sub Fascial Hammock	Unknown	463704007	Obex	16628
Unknown	12-May-14	Chronic pain and dyspareunia	American Medical Systems	Monarc Sub Fascial Hammock	Unknown	403223047	Obex	16684

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Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
Unknown	11-Aug-2014	Recurrent urinary tract infections	Ethicon	Gynaecare TVT	810041B	3157220	Johnson & Johnson Medical NZ	17295

Reports - Pelvic Organ Prolapse (POP) Surgical Mesh Devices

Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
30-Jan-04	14-Dec-12	Pain	Atrium	Prolite Mesh	1000306-00	22222799	Atrium NZ	14021
23-Sep-04	9-Oct-13	On-going pain and mesh erosion	Ethicon	Gynaemesh	Unknown	Unknown	Johnson & Johnson Medical NZ	15688
13-Apr-05	26-Sep-13	On-going pain and mesh erosion	Ethicon	Gynaemesh PS	Unknown	Unknown	Johnson & Johnson Medical NZ	15441
17-Jan-06	26-Sep-13	On-going pain and mesh erosion	Ethicon	Prolift Mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	15437
1-Feb-06	19-Nov-12	Pain	Ethicon	Gynaemesh PS	Unknown	Unknown	Johnson & Johnson Medical NZ	13819
17-Mar-06	28-Sep-06	Pain, vaginal bleeding, and discharge	Unknown	Unknown	Unknown	Unknown	Unknown	4866
19-May-06	15-Apr-08	Vaginal damage/injury/tear	American Medical Systems	Apogee System with IntePro	72404025	447138028	Obex	6111

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Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
7-Jun-06	15-May-14	Erosion of mesh into vagina	Ethicon	Gynacare mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	16438
15-Jul-06	15-Apr-08	Vaginal damage/injury/tear	American Medical Systems	Perigee System with IntePro	72404046	424923013	Obex	6111
19-Jul-06	15-Apr-08	Vaginal damage/injury/tear	Unknown	Unknown	Unknown	Unknown	Unknown	6111
6-Sep-06	9-Sep-13	On-going pain and mesh erosion	Ethicon	Prolift Mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	15611
7-Sep-06	20-Mar-13	Pain & incontinence	Ethicon	Prolift Mesh	PERT01	1391342	Johnson & Johnson Medical NZ	14391
14-Sep-06	15-Apr-08	Vaginal damage/injury/tear	Unknown	Unknown	Unknown	Unknown	Unknown	6111
11-Dec-06	15-Apr-08	Vaginal damage/injury/tear	Ethicon	Gynaecare Gynaemesh PS	GPSL L02	XBE363	Johnson & Johnson Medical NZ	6111
18-Jan-07	15-Apr-08	Urinary retention	Ethicon	Gynaecare Gynaemesh PS	GPSL	XAD746	Johnson & Johnson Medical NZ	6111

Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
25-Jan-07	15-Apr-08	Vaginal damage/injury/tear	Ethicon	Gynaecare Gynaemesh PS	GPSL	XAD746	Johnson & Johnson Medical NZ	6111
17-Sep-07	17-Sep-07	Unknown	Ethicon	Gynaecare surgical mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	5620
1-Mar-08	20-Mar-13	Pain, incontinence	Ethicon	Gynemesh PS	Unknown	ZLB416	Johnson & Johnson Medical NZ	14392
11-Mar-08	27-Sep-13	On-going pain and mesh erosion	Ethicon	Gynemesh PS	Unknown	Unknown	Johnson & Johnson Medical NZ	15447
13-Mar-08	15-Apr-08	Vaginal damage/injury/tear	Ethicon	Gynaecare Gynaemesh PS	PFRT01	2894572	Johnson & Johnson Medical NZ	6111
17-Jun-08	14-Nov-08	Erosion	American Medical Systems	Perigee System	72404046	546807022	Obex	6834
4-Aug-08	30-Sep-13	On-going pain and mesh erosion	Ethicon	Prolift Mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	15455
15-Oct-08	17-Jul-09	Erosion into vagina	Ethicon	Gynaecare Gynaemesh PS	GPSL.KLOZ	ZHE902	Johnson & Johnson Medical NZ	7660

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Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
27-Nov-08	12-Jun-13	Erosion	American Medical Systems	Perigee System with IntePro	Unknown	Unknown	Obex	14817
28-Nov-08	20-Sep-13	On-going pain and mesh erosion	Ethicon	Gynemesh PS	Unknown	Unknown	Johnson & Johnson Medical NZ	15406
31-Mar-09	24-Sep-13	On-going pain and mesh erosion	Ethicon	Prolift Mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	15435
8-Dec-09	11-Feb-10	Erosion into vagina	American Medical Systems	Intepro Lite	Unknown	Unknown	Obex	8423
15-Jan-10	7-Jan-11	Pain	Ethicon	Gynaecare Prolift Anterior Kit	PFRA01	Unknown	Johnson & Johnson Medical NZ	10003
24-Mar-10	12-Feb-13	Pain	Ethicon	Ultrapro Mesh	UMN3	BL3MQJRO	Johnson & Johnson Medical NZ	14217
24-Mar-10	9-Jul-13	Erosion and mesh shrinkage	Ethicon	Ultrapro Mesh	UMN3	B18MQJRO	Johnson & Johnson Medical NZ	14978
20-May-10	7-Nov-14	Mesh shrinkage	American Medical Systems	Perigee	Unknown	Unknown	Obex	17724

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Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
18-Nov-10	15-May-14	Erosion of mesh into vagina	Ethicon	Prolift Mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	16439
10-Feb-11	9-Oct-13	On-going pain and mesh erosion	Ethicon	Prosima Pelvic Floor Repair System	Unknown	Unknown	Johnson & Johnson Medical NZ	15676
2-Sep-11	7-Nov-11	Vaginal damage/injury/tear	Atrium	Prolite Mesh	1000306-00	10452843	Atrium NZ	11452
13-Sep-11	29-Jan-13	Erosion causing pain, discharge, infection	American Medical Systems	Elevate	Unknown	Unknown	Obex	14420
29-Sep-11	26-Sep-13	On-going pain and mesh erosion	Ethicon	Prolift Mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	15443
1-Jun-12	3-Jul-13	On-going pain	Ethicon	Unknown	Unknown	Unknown	Johnson & Johnson Medical NZ	15134
31-Aug-12	29-Jan-13	Erosion into bladder	Boston Scientific	Uphold	Unknown	Unknown	Boston Scientific	14419
28-Sep-12	20-Aug-13	Patient experienced unknown injury	Boston Scientific	Uphold	M0068317080	Unknown	Boston Scientific	15274

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Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
28-Nov-12	13-Feb-14	On-going pain	Boston Scientific	Uphold	M0068317080	ML00000192	Boston Scientific	16229
8-May-13 (prev. dated 2-Aug-2013)	2-Aug-13	Erosion into vagina	Boston Scientific	Uphold	M0068317080	Unknown	Boston Scientific	15118
25-May-13	2-May-14	Vaginal, bowel and hip pain and nausea	Ethicon	Ultrapro Mesh	UMN3	BD8JXWRO	Johnson & Johnson Medical NZ	16629
15-Nov-13	31-Jul-14	Erosion of mesh into pelvic organs	Ethicon	Gynaecare Mesh	Unknown	Unknown	Johnson & Johnson Medical NZ	17153
Unknown	15-Jan-14	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	16038
Unknown	12-Mar-14	Erosion of mesh into vagina	Caldera Medical	Ascend AC Mesh	CAL-AC02	104021	Device Technologies NZ	16437
Unknown	20-Jun-14	Severe pain and bleeding following intimacy	Unknown	Unknown	Unknown	Unknown	Unknown	16890
Unknown	3-Jul-14	Intermittent sharp pain in vagina	American Medical Systems	Perigee	720003-02	633795008	Obex	16962

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Reports - Hernia Mesh Devices

Event Date	Report Date	Adverse Event	Brand	Device	Model	Batch	Sponsor	Medsafe Ref
13-Dec-08	2-Dec-09	Perforation of Bowel	US Surgical	Surgipro Prolene Mesh	Unknown	Unknown	Covidien	7972
24-Dec-09	5-Jan-10	Bowel Obstruction	Bard	Bard Composix Kugel Mesh	10205	HUTD1709	Obex	8257
15-Dec-10	5-Jan-11	Out of box failure. Not used on patient.	Ethicon	Proceed Ventral Patch	PVPM	CA8PBKZO	Johnson & Johnson Medical NZ	9994
13-Oct-11	25-Oct-11	Out of box failure. Not used on patient.	Ethicon	Proceed Ventral Patch	Unknown	DH8CKTZ0	Johnson & Johnson Medical NZ	11372
26-Oct-11	26-Oct-11	Bowel obstruction at implant site	Ethicon	Proceed Ventral Patch	Unknown	Unknown	Johnson & Johnson Medical NZ	11380
1-Jan-12	12-Sep-12	Scarring	Ethicon	Physiomesh Composite	PHY1520V	Unknown	Johnson & Johnson Medical NZ	13494
16-Nov-13	29-Nov-13	Mesh tore 2 days post implant	Covidien	Parietex	PCO3020FX	PLL00147	Covidien	15777

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Reporting a Medical Device Adverse Event

Adverse events that cause injury and that are associated with medical devices should be reported to Medsafe. Such events may be indicative of a quality or safety issue that needs to be addressed in some form. By reporting these to Medsafe seemingly isolated incidents may be collated and responded to.

Summary Information from these reports will be published in the Joint Adverse Events Notification System (JAENS-MD) on the ANZTPA website.
http://www.anztpa.org/devices/summary/search

Who can report an adverse event?

Anyone can submit an adverse event report. Patients, caregivers, healthcare professionals and suppliers are all encouraged to lodge an adverse event report if an incident has occurred and there is a concern about the safety of the device or its use.

Adverse Event Reporting Form (Healthcare Professionals, Patients)

Healthcare professionals, patients, and carers lodging adverse event reports with Medsafe should use the joint Medsafe-TGA adverse event reporting form.

Completed adverse event report forms may be submitted to Medsafe by any of the following ways.

- Fax to 04-819-6806
- Email to devices@moh.govt.nz
- Post to the Compliance Management Branch, Medsafe, PO Box 5013, Wellington, 6415.

The Medsafe-TGA medical device adverse event reporting form is available for download from the Medsafe website at the link below:
http://www.medsafe.govt.nz/downloads/device.doc

Investigation of reports

All adverse events are reviewed by Medsafe with both safety and quality issues being considered. As part of these reviews further information may be requested from the reporter and/or the device supplier. If necessary, Medsafe may also contact overseas regulatory agencies to ascertain whether they have received similar reports about the device.

All reports received are retained by Medsafe.