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

August 2017

MINISTRY OF HEALTH
MANATU HAUORA

New Zealand Government

Document History

Version Number	Revision Date	Summary of Changes
0	Dec-2013	Reports received to 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
4	Jul-2015	Addition of reports received to Jun-2015 Removal of duplicate reports POP report (Ref #14978. Original report #14217.) Following an audit of all reports, Event Dates corrected to reflect the implant date of the device (where this information has been provided) Summary of reports received updated
5	May-2016	Addition of reports received to Mar- 2016 Summary of reports received updated Removal of a duplicate report (#18962)
6	Sept-2016	Addition of reports received to Sept-2016 Summary of reports received updated Event Dates corrected to reflect the implant date of the device (where this information has been provided)
7	Dec-2016	Addition of reports received to Nov-2016 Summary of reports received updated
9	Aug-2017	Addition of reports received up to 21 July-2017 Corrections and additions to reported adverse events as a result of data verification. Reformatted tables to better identify date of implant, and date of report received at Medsafe.

		Summary of devices supplied in New Zealand for the period 1 Jan 2005 to 31 March 2017

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.

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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 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:

www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp

Report Period

This report covers adverse event reports received by Medsafe from 2005 until 21 July 2017.

Key to data tables

The table below explains the information contained in this summary.

Guide to table Field	Explanation
Report Date	Date the report was received by Medsafe
Implant Date	Date the device was originally implanted in the patient
Adverse Event	Description of adverse event experienced by patient
Sponsor	The New Zealand supplier of the device
Brand Name	Model name or family name of device
Model	Manufacturer's model number/order code of device (where known)
Batch/Lot	Manufacturer's batch/lot number of device (where known)
Medsafe Reference	Reference number for the report in the Medsafe post market investigation database.

Summary of data supplied to Medsafe

Summary of Reports

Since 2005 Medsafe has received a total of 144 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	74
Surgical Mesh (Pelvic Organ Prolapse, POP)	61
Surgical Mesh (hernia)	48
	183

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

Suppliers of devices (sponsors)	27
Manufacturer of device	2
Healthcare professionals	4
Accident Compensation Corporation (ACC)	118
Patients	32
	183

To better understand the rate of incidents being reported Medsafe requested information about the quantity of devices supplied in New Zealand between 2005 and March 2017. 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 tables

Table 1 summarises the number of different devices supplied in New Zealand. Table 2 summarises the number of adverse reports submitted to Medsafe.

Table 1: Summary of devices supplied in New Zealand for the period 1 Jan 2005 to 31 March 2017

Product Grouping	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017[1]	Total Units
Urinary Incontinence Products (male)	0	0	0	24	37	40	40	56	60	2	29	39	7	334
Urinary Incontinence Products (female)	1314	1533	1721	1625	1844	1833	1761	1924	2131	1614	1302	1142	279	20023
Pelvic Organ Prolapse Products	557	591	568	842	1011	755	679	597	377	262	205	159	36	6639
Hernia products in relation to groin, ventral repairs	3756	4212	3460	2780	2661	2467	2805	3860	3911	3335	3368	2800	1,015	40430
Total	**5627**	**6336**	**5749**	**5271**	**5553**	**5095**	**5285**	**6437**	**6479**	**5213**	**4904**	**4140**	**1337**	**67426**

[1] to 31 March 2017.

Table 2 Summary of adverse event reports received by Medsafe by year report received for the period 1 Jan 2005 to 21 July 2017

Product Grouping	2005 (reports)	2006 (reports)	2007 (reports)	2008 (reports)	2009 (reports)	2010 (reports)	2011 (reports)	2012 (reports)	2013 (reports)	2014 (reports)	2015 (reports)
Stress Urinary Incontinence Devices	-	-	-	6	3	-	2	-	7	6	27
Pelvic Organ Prolapse Devices	-	1	-	6	1	1	2	2	19	10	8
Hernia Devices	-	-	-	-	2	-	1	2	1	-	3

Product Grouping	2016 (reports)	2017 (reports)	Total number (reports)
Stress Urinary Incontinence Devices	9	14	**74**
Pelvic Organ Prolapse Devices	5	6	**61**
Hernia Devices	6	33	**48**

Report summaries

The following tables provide summary data on the adverse reaction reports provided to Medsafe. Table 3 summarises reports concerning stress urinary incontinence devices. Table 4 summarises reports concerning pelvic organ prolapse surgical mesh reports provided to Medsafe. Table 5 summarises reports concerning hernia mesh device reports provided to Medsafe.

Table 3: Stress Urinary Incontinence (SUI) Devices

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
Unknown	2/04/2015	Mesh erosion	Transvaginal Tape	Unknown	Unknown	Unknown	18697
1/01/2001	11/05/2015	Erosion	Unknown TVT mesh	Unknown	Unknown	Unknown	18551
5/05/2003	17/06/2015	Abdominal pain	Ethicon Gynecare TVT device	810041	1038190	Johnson & Johnson Medical New Zealand Ltd	18693
29/11/2004	11/07/2011	Infection	Monarc Subfascial Hammock	Unknown	Unknown	Obex Medical Ltd	10926
3/12/2004	12/05/2014	Chronic pain and dyspareunia	Monarc Subfascial Hammock	Unknown	403223047	Obex Medical Ltd	16684
1/01/2005	3/02/2009	Infection	Tyco IVS Tunneller	Unknown	Unknown	Covidien NZ Ltd	7036
13/01/2005	13/03/2014	Mesh erosion	Tyco IVS Tunneller	Unknown	Unknown	Covidien NZ Ltd	16438
6/05/2005	3/10/2011	Bladder perforation	Ethicon Gynecare TVT Device	810041B	1207535	Johnson & Johnson Medical New Zealand Ltd	11276
5/08/2005	16/09/2008	Infection	TVT Prolene	Unknown	Unknown	Unknown	6607
30/10/2005	15/04/2008	Protruding tape	SPARC Sling	72403657	375289008	Obex Medical Ltd	6111

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
5/07/2006	15/04/2008	Erosion, vaginal tear	Ethicon Gynecare TVT	810041B	1319566	Johnson & Johnson Medical New Zealand Ltd	6111
19/07/2006	15/04/2008	Blood loss, procedural complications	Ethicon Gynecare TVT	810081	2906367	Johnson & Johnson Medical New Zealand Ltd	6111
7/09/2006	20/03/2013	Lower body pain, incontinence	Tyco Healthcare IVS Tunneler	IVS-02	04H-109	Covidien NZ Ltd	14391
10/10/2006	4/08/2016	Extrusion of the tape	TVT Mesh	Unknown	Unknown	Unknown	20585
24/11/2006	2/05/2014	Ongoing leg and vaginal pain	Monarc Subfacial Sling	72403831	463704007	Obex Medical Ltd	16628
27/11/2006	12/08/2016	Pain and incontinence	AMS Monarc Sling System	Unknown	Unknown	Obex Medical Ltd	20615
1/01/2007	9/02/2015	Mesh exposure and erosion	(AMS) Apogee and Perigee mesh Systems	Unknown	Unknown	Unknown	18402
1/01/2007	11/05/2015	Tissue damage, pelvic pain	Tyco IVS Tunneller	IVS-02M	06C269	Covidien NZ Ltd	18553
18/01/2007	15/04/2008	Urinary retention	Gynecare Gynamesh PS	GPSL	XAD746	Johnson & Johnson Medical New Zealand Ltd	6111
23/08/2007	4/12/2015	Bilateral erosions	Mesh TVT-O (tension free vaginal tape obturator) SUI	Unknown	Unknown	Unknown	20597

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
11/10/2007	15/04/2008	Ongoing pain, erosion	Textile Hi-tec	THT 81270	5042904	Surgical Supplies Limited NZ	6111
1/01/2008	11/08/2014	Erosion, recurrent Urinary infections	Gynecare TVT Tape/ Colposuspension	810041B	3157220	Johnson & Johnson Medical New Zealand Ltd	17295
1/01/2008	11/05/2015	Erosion, pelvic pain	Gynecare PROLIFT Posterior Pelvic Floor Repair System	PFRP01	3120185	Johnson & Johnson Medical New Zealand Ltd	18550
17/10/2008	2/04/2017	Infection	Monarc TVT Sling (SUI)	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	21287
27/11/2008	12/06/2013	Mesh erosion	AdVance Transorburator Sling	Unknown	Unknown	Obex Medical Ltd	14817
28/11/2008	20/09/2013	Pain and mesh erosion	Ethicon TVT Obturator System	810081	Unknown	Johnson & Johnson Medical New Zealand Ltd	15406
2/12/2008	20/03/2009	Small abscess, infection	Ethicon TVT Obturator System	810081	Unknown	Johnson & Johnson Medical New Zealand Ltd	7224
18/12/2008	26/09/2013	Pain and mesh erosion	Ethicon TVT Obturator System	810081	Unknown	Johnson & Johnson Medical New Zealand Ltd	15442
1/01/2009	9/02/2015	Pain and mesh erosion	Monarc Transobturator Tape	Unknown	Unknown	Unknown	18400

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
1/03/2009	9/02/2015	Abdominal pain, erosion	Monarc tape	Unknown	Unknown	Unknown	18404
4/04/2009	11/02/2013	Constant pain, urinary retention	SPARC Transvaginal Sling	Unknown	Unknown	Obex Medical Ltd	14192
18/05/2009	20/07/2015	Mesh erosion	Gynecare TVT Obturator System	810081	3256677	Johnson & Johnson Medical New Zealand Ltd	18909
24/06/2009	28/07/2009	Pain	Ethicon TVTO System	810081	Unknown	Johnson & Johnson Medical New Zealand Ltd	7692
04/06/2007, 20/09/2009	1/12/2015	Urethral stenosis	SPARC Sling/TVT Tape/Colposuspension	72403657	486974039, 585202027	Unknown	20593
3/12/2009	9/02/2015	Tissue damage	Ethicon Transobturator tape	Unknown	Unknown	Unknown	18409
1/01/2010	9/02/2015	Vaginal ulcer	Trans Vaginal Tape (TVT)	Unknown	Unknown	Unknown	18412
24/05/2010	30/04/2016	Severe pains	AMS Monarc Sling System	72403831	640798026	Obex Medical Ltd	20229
2/08/2010	20/08/2013	Unknown injury	Obtryx Single System Sling	Unknown	Unknown	Boston Scientific NZ Ltd	15273
18/11/2010	12/03/2014	Tape erosion	Ethicon Gynecare TVT Tape	810041B	3422079	Johnson & Johnson Medical New Zealand Ltd	16439
8/12/2010	7/06/2017	Mesh erosion	TVT Tape	Unknown	Unknown	Unknown	21508
1/01/2011	9/06/2016	Erosion	TVT Tape/Colposuspension	Unknown	Unknown	Unknown	20589

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
26/05/2011	17/06/2015	Mesh exposure	Unknown TVT device	Unknown	Unknown	Unknown	18696
9/11/2011	9/02/2015	Erosion	Trans Vaginal Tape (TVT)	Unknown	Unknown	Unknown	18405
1/01/2012	13/03/2013	Mesh erosion	Ethicon Gynecare TVT Obturator	810081	Unknown	Johnson & Johnson Medical New Zealand Ltd	14357
8/02/2012	27/03/2017	Mesh extrusion	Trans vaginal tape (TVT)	Unknown	Unknown	Unknown	21253
26/03/2012	16/05/2017	Mesh stricture & erosion	Unknown	Unknown	Unknown	Unknown	21435
18/06/2012	6/06/2017	Vaginal discharge	Unknown	Unknown	Unknown	Unknown	21498
20/09/2012	27/03/2017	Dyspareunia due to erosion	Tension free trans vaginal tape	Unknown	Unknown	Unknown	21252
31/10/2012	30/08/2016	Vaginal discharge and discomfort	Smith & Nephew Monarc Sling	72404193	787481035	Smith & Nephew Ltd	20595
6/05/2013	6/04/2017	Erosion	Ehticon Gynecare TVT Sling (for SUI)	810041B	3668166	Johnson & Johnson Medical New Zealand Ltd	21270
18/06/2013	11/04/2016	Abdominal and pelvic pain, erosion	Ethicon Gynecare Exact TVTRL	Unknown	3683049	Johnson & Johnson Medical New Zealand Ltd	20592
29/08/2013	6/03/2015	Mesh erosion	Unknown TVT device	Unknown	Unknown	Unknown	18692
5/09/2013	24/05/2017	Unable to void	Monarc Subfascial Hammock	72403831	826729042	Obex Medical Ltd	21555

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
7/10/2013	8/07/2014	Bladder infections, pain, erosion	A M I Multi-Purpose Sling	AMI CE0297	Batch: PFR5021 Lot: 130362	Endoventure Ltd	16955
12/12/2013	12/08/2015	Urethral-vaginal fistula, erosion, pain	Transvaginal (TVT) Tape	Unknown	Unknown	Unknown	19132
1/02/2014	8/06/2015	Mesh erosion, voiding dysfunction	Ethicon Gynecare TVT Exact device	TVTRL	Unknown	Johnson & Johnson Medical New Zealand Ltd	18642
11/03/2014	6/01/2015	Mesh exposure	Transobturator Sling	Unknown	Unknown	Unknown	18240
1/04/2014	6/01/2015	Incontinence, erosion	Tension Free Vaginal Tape	Unknown	Unknown	Unknown	18234
16/04/2014	19/02/2017	Pain and trouble urinating	Gynecare TVT Exact Continence System	TVTRL	3740009	Unknown	21125
1/07/2014	20/07/2015	Mesh erosion	Unknown TVT device	Unknown	Unknown	Unknown	18910
21/07/2014	11/11/2015	Erosion of vaginal mesh	AMS SPARC Sling	72403657	821252079	Unknown	19469
1/08/2014	8/06/2015	Mesh exposure	Ethicon Gynecare TVT Exact device	TVTRL	3746880	Johnson & Johnson Medical New Zealand Ltd	18641
21/08/2014	9/02/2015	Mesh erosion	Alcon Monarc Mesh	72403831	858288032	Obex Medical Ltd	18411
3/10/2014	20/07/2015	Vaginal pain, erosion	Monarc Subfascial Hammock	72403831	778198015	Obex Medical Ltd	18907
23/03/2015	7/09/2015	Mesh exposure	Gynecare Tension Free Blue ProleneVaginal Tape	810041B	3791320	Johnson & Johnson Medical New Zealand Ltd	19121

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
30/03/2015	11/11/2015	Erosion	Ethicon Gynecare TVT	810041B	37954484	Johnson & Johnson Medical New Zealand Ltd	19477
8/04/2015	7/06/2017	Right groin pain	TVT-O	Unknown	Unknown	Unknown	21510
9/04/2015	9/02/2016	Exposed mesh	Ethicon Gynecare TVT Abbrevo System	Unknown	3783336	Johnson & Johnson Medical New Zealand Ltd	20591
20/08/2015	7/06/2017	Pudendal & Obturator nerve neuropraxia	Monarch Tape	Unknown	Unknown	Unknown	21507
9/09/2015	11/04/2017	Severe pain	Ethicon Gynecare TVT-O Sling	810081	3834040	Unknown	21316
24/09/2015	9/02/2016	Erosion	Ethicon TVT Tape	Unknown	Unknown	Unknown	19927
14/12/2015	4/08/2016	Exposed TVT	Gynecare TVT Exact Continence System	TVTRL	3868643	Johnson & Johnson Medical New Zealand Ltd	20586
29/02/2016	20/05/2017	Pain in groin	Monarc Sling	Unknown	Unknown	Unknown	21454
25/05/2016	16/05/2017	Tape erosion	TVT Tape	Unknown	Unknown	Unknown	21433

Table 4: Reports - Pelvic Organ Prolapse (POP) Surgical Mesh Devices

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
1/01/2008	11/05/2015	Pelvic pain, incontinence	Ethicon Gynecare TVT system	810081	2922936	Johnson & Johnson Medical New Zealand Ltd	18550
1/01/2008	11/05/2015	Pelvic pain, incontinence	Prolift Pelvic Floor Repair System	PFRA01	1332543	Johnson & Johnson Medical New Zealand Ltd	18550
1/03/2008	20/03/2013	Pain and incontinence	Gynemesh Prolene Soft Mesh	GPSLL02	ZLB416	Johnson & Johnson Medical New Zealand Ltd	14392
1/03/2015	7/06/2017	Recurrent UTI	Uphold Mesh	Unknown	Unknown	Unknown	21502
1/06/2012	3/07/2013	Pain and discomfort	Ethicon Mesh	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15134
1/12/2008	7/01/2011	Pain	Prolift Pelvic Floor Repair System	PFRA01	3132584	Johnson & Johnson Medical New Zealand Ltd	10003
10/02/2011	9/10/2013	Pain and erosion	Prosima Pelvic Floor Repair System	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15676
10/03/2003	23/02/2017	Pain in pelvic region	Polypropylene tape	Unknown	Unknown	Unknown	21142
11/03/2008	27/09/2013	Pain and erosion	Ethicon Gynemesh PS surgical mesh	GPSL	ZLB416	Johnson & Johnson Medical New Zealand Ltd	15447
11/05/2010	7/11/2016	Superficial mesh	Vaginal Pro-lift Mesh	Unknown	Unknown	Unknown	20849
11/05/2012	12/03/2014	Mesh erosion	Caldera Ascend AC Mesh	10-005-02 Rev A	104021	Mediflex Surgical Products	16437

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
11/07/2008	2/10/2015	Rectal bleeding, erosion	Ethicon Gynecare Vaginal mesh	Unknown	Unknown	Unknown	19236
11/08/2009	2/05/2014	Bowel and hip pain, nausea	Ethicon ULTRAPRO Mesh	UMN3	BD8JXWRO	Johnson & Johnson Medical New Zealand Ltd	16629
11/12/2006	15/04/2008	Erosion	Gynecare Gynemesh PS	GPSL L02	XBE363	Johnson & Johnson Medical New Zealand Ltd	6111
13/01/2005	13/03/2014	Bleeding and pain, erosion	Ethicon Gynecare mesh	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	16438
13/03/2008	15/04/2008	Mesh extrusion	Gynecare Gynemesh PS	810081	1307149	Johnson & Johnson Medical New Zealand Ltd	6111
13/04/2005	26/09/2013	Pain and erosion	Ethicon Gynemesh PS surgical mesh	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15441
13/09/2011	1/02/2012	Nocturnal urinary incontinence, pain, infection, erosion	AMS Elevate Mesh Repair	720093-01	Unknown	Obex Medical Ltd	14420
13/09/2011	16/05/2017	Haematoma	Unknown	Unknown	Unknown	Unknown	21447
15/07/2006	15/04/2008	Haematoma, erosion	AMS Apogee & Perigee Systems	72404046	424923013	Obex Medical Ltd	6111
16/10/2007	17/07/2009	Mesh erosion	ETHICON Gynemesh PS	GPSL.LOZ	ZHE902	Johnson & Johnson Medical New Zealand Ltd	7660
17/01/2006	25/09/2013	Pain and erosion	Prolift Pelvic Floor Repair System	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15437

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
17/06/2008	11/11/2008	Mesh erosion	AMS Perigee mesh with IntePro	72404046	546807022	Obex Medical Ltd	6834
17/11/2009	7/11/2011	Erosion, vaginal tear	Atrium Prolite Mesh	1000306-00	10452843	Atrium NZ Limited	11452
18/05/2009	20/07/2015	Mesh erosion	Ethicon PROLIFT Pelvic Floor Repair System	PFRT01	3256766	Johnson & Johnson Medical New Zealand Ltd	18909
18/11/2010	12/03/2014	TVT tape eroded	Prolift Pelvic Floor Repair System	PFRA01	3389813	Johnson & Johnson Medical New Zealand Ltd	16439
19/04/2010	7/09/2015	Mesh penetration into rectum	AMS Interpro-Y Graft Mesh	Unknown	Unknown	Unknown	19123
19/05/2006	15/04/2008	Bleeding and discharge, erosion	AMS Apogee & Perigee Systems	72404025	447138028	Obex Medical Ltd	6111
20/05/2010	4/07/2014	Pain and infection	Perigee polypropylene Mesh	720003-02	633796008	Obex Medical Ltd	16962
20/05/2010	7/11/2014	Chronic pain	AMS Perigee System	Unknown	Unknown	Obex Medical Ltd	17724
20/10/2009	15/02/2010	Erosion, infection	AMS Intepro Lite surgical mesh	Unknown	Unknown	Obex Medical Ltd	8423
21/09/2008	9/02/2016	Mesh exposure	Ethicon Prolift Mesh	Unknown	Unknown	Unknown	19943
21/12/2004	31/07/2014	Erosion	Ethicon Gynecare Mesh 3/0 Ethibond	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	17153

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
23/09/2004	19/11/2012	Further prolapse, pain	Gynemesh PS Surgical Mesh	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	13819
23/09/2004	9/10/2013	Pain and mesh erosion	Gynemesh	Unknown	Unknown	Johnson & Johnson Medical Pty Ltd	15688
24/03/2010	12/02/2013	Pain	Ethicon ULTRAPRO Mesh	UMN3	BL8MQJRO	Johnson & Johnson Medical New Zealand Ltd	14217
24/03/2010	8/07/2013	Pain and inflammation	Ultra Pro Mesh UMN3 Ethicon	UMN3	BL8MQJRO	Johnson & Johnson Medical New Zealand Ltd	14978
24/03/2011	30/08/2016	Exposed mesh	Prolift Pelvic Floor Repair System	APRA01	3413180	Johnson & Johnson Medical New Zealand Ltd	20594
25/01/2007	15/04/2008	Mesh erosion, urinary retention	Gynecare Gynemesh PS	GPSL	XAD746	Johnson & Johnson Medical New Zealand Ltd	6111
25/05/2010	20/06/2014	Severe pain and bleeding	Surgical mesh	Unknown	Unknown	Unknown	16890
25/09/2008	30/04/2016	Infection, pain, mesh exposure	AMS Apogee & Perigee Systems	72404025	536677023	Obex Medical Ltd	20230
26/01/2012	27/03/2017	Mesh extrusion	PROLIFT Vaginal Mesh	Unknown	Unknown	Unknown	21254
27/11/2008	12/06/2013	Erosion	Apogee & Perigee Systems with Intepro	Unknown	Unknown	Obex Medical Ltd	14817
28/09/2012	20/08/2013	Unknown injury	Uphold Vaginal Support System	M0068317080	Unknown	Boston Scientific NZ Ltd	15274

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
28/09/2012	13/02/2014	Severe pain	Perigree Monarc Uphold Subfascial Hammock	M0068317080	ML00000192	Boston Scientific NZ Ltd	16229
28/11/2008	20/09/2013	Pain and erosion	Ethicon Gynemesh PS	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15406
29/05/2006	2/05/2017	Mesh erosion	AMS Apogee & Perigee Systems	Unknown	Unknown	Unknown	21369
29/05/2006	2/05/2017	Mesh erosion	AMS Monarc Sling System	Unknown	Unknown	Unknown	21369
29/09/2011	26/09/2013	Pain and erosion	Prolift Pelvic Floor Repair System	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15443
31/03/2009	24/09/2013	Pain and erosion	Prolift Pelvic Floor Repair System	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15435
31/08/2012	29/01/2013	Erosion	Uphold Vaginal Support System	M0068317080	ML00000705	Boston Scientific NZ Ltd	14419
4/08/2008	24/09/2013	Pain and erosion	Prolift Pelvic Floor Repair System	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15455
5/05/2003	6/03/2015	Abdominal pain, erosion	Ethicon VYPRO II Mesh, 15x10cm	PVM2N3	RH8GTQD0	Johnson & Johnson Medical New Zealand Ltd	18693
6/08/2002	8/06/2015	Mesh erosion	Ethicon Gynemesh PROLENE Mesh	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	18637
6/09/2006	9/10/2013	Pain and erosion	Prolift Mesh	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	15611

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
7/09/2006	20/03/2013	Lower body pain, incontinence	Ethicon Gynecare Prolift Mesh	PERT01	1391342	Johnson & Johnson Medical New Zealand Ltd	14391
7/09/2006	2/09/2016	Infection	Prolift Pelvic Floor Repair System	PFRT01	1391342	Johnson & Johnson Medical New Zealand Ltd	20646
8/05/2013	2/08/2013	Erosion	Uphold Vaginal Support System	M0068317080	Unknown	Boston Scientific NZ Ltd	15118
9/03/2007	8/06/2015	Bleeding and discharge, erosion	Prolift Pelvic Floor Repair System	PFRT01	2960373	Johnson & Johnson Medical New Zealand Ltd	18638
Unknown	28/09/2006	Tissue erosion, pain, bleeding	Surgical mesh for vaginal application	Unknown	Unknown	Unknown	4866
Unknown	15/01/2014	Experiencing complications	Surgical Mesh	Unknown	Unknown	Unknown	16038

Table 5: Hernia Mesh Devices reports

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
Unknown	26/10/2011	Bowel obstruction	PROCEED Ventral Patch	Unknown	Unknown	Johnson & Johnson Medical Pty Ltd	11380
Unknown	16/05/2017	Blood vessel perforation	Unknown	Unknown	Unknown	Unknown	21438
Unknown	7/06/2017	Wound infection	Unknown	Unknown	Unknown	Unknown	21511
Unknown	7/06/2017	Infected mesh	Unknown	Unknown	Unknown	Unknown	21512
1/08/2000	7/10/2009	Bowel perforation	Surgipro Prolene Mesh	Unknown	Unknown	Covidien NZ Ltd	7972
20/10/2003	8/06/2015	Bowel fistula, erosion	ETHICON Prolene Mesh	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	18640
1/01/2004	25/05/2015	fistula, organ failure	Ethicon Prolene 6" x 6" mesh	Unknown	Unknown	Johnson & Johnson Medical New Zealand Ltd	18598
30/01/2004	14/12/2012	Immense pain	Atrium Medical Prolite Mesh	1000306-00	22222799	Atrium NZ Limited	14021
1/01/2005	21/05/2017	Recurrence of hernia	Unknown	Unknown	Unknown	Unknown	21455
12/03/2007	15/08/2016	Recurrence of hernia	Surgipro Mesh	SPM35	A6G631	Unknown	20515
21/12/2009	31/12/2009	Bowel obstruction	Bard Composix Kugel Mesh	10205	HUTD1709	Obex Medical Ltd	8257
11/01/2010	15/08/2016	Mesh separated	Surgipro Mesh	SPMM66	A9F0398	Unknown	20514
13/08/2010	16/05/2017	Scar tissue	Unknown	Unknown	Unknown	Unknown	21436
2/06/2011	7/06/2017	Infection	Unknown	Unknown	Unknown	Unknown	21503
30/06/2011	11/04/2016	Infection	TycoHealthcare Parietex	TEC1510	SLE00394	Covidien NZ Ltd	20590

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
28/10/2011	1/04/2017	Severe pain	Atrium Prolite mesh	1000306-00	10749439	Atrium NZ Limited	21284
1/01/2012	12/09/2012	Scarring	Physiomesh Composite mesh	PHY1520V	Unknown	Johnson & Johnson Medical New Zealand Ltd	13494
2/03/2012	1/04/2017	Incisional hernia	Atrium CQur Mesh	Unknown	Unknown	Atrium NZ Limited	21285
22/05/2012	16/05/2017	Fluid collection	Unknown	Unknown	Unknown	Unknown	21446
21/05/2013	16/05/2017	Infection	Unknown	Unknown	Unknown	Unknown	21443
30/10/2013	14/09/2016	Foreign body reaction	TYCO Parietene Surgical mesh	Unknown	SNF0078, SND0974	Covidien NZ Ltd	20649
16/11/2013	29/11/2013	Mesh tore	Covidien Parietex PCO Mesh	PCO3020OSX	PLL00147	Covidien NZ Ltd	15777
23/05/2014	4/12/2016	Mesh shrunk	C-QUR V-Patch	Unknown	10752128082	Maquet Australia Pty Ltd (NZ)	20596
28/05/2014	17/05/2016	Failure to integrate forming a hard mass	Permacol Biological mesh	Unknown	Unknown	Unknown	20198
14/07/2014	16/05/2017	Pain	Unknown	Unknown	Unknown	Unknown	21445
4/08/2014	9/06/2016	Pain and nausea.	J&J Vypro mesh	VYPRO II Mesh; PVN2P3	GK8HQGQ0	Johnson & Johnson Medical New Zealand Ltd	20588
24/03/2015	16/05/2017	Small recurrence	Unknown	Unknown	Unknown	Unknown	21449
23/11/2015	1/04/2017	Constant pain.	Ethicon Physiomesh	PHY1520V	JHBGPMCO	Unknown	21286
15/01/2016	18/05/2017	Infection	Unknown	Unknown	Unknown	Unknown	21452
16/02/2016	16/05/2017	Tissue loss	Unknown	Unknown	Unknown	Unknown	21437
28/04/2016	9/01/2017	Infection	Parietex	TECR1510	SPK0527X	Unknown	21256

Implant Date	Report Date	Adverse Event	Brand Name	Model	Batch/Lot	Sponsor	Medsafe Reference
3/06/2016	17/05/2017	Recurrence of hernia	Unknown	Unknown	Unknown	Unknown	21451
28/06/2016	16/05/2017	Persistent pain	Unknown	Unknown	Unknown	Unknown	21448
9/07/2016	7/06/2017	Wound infection	Unknown	Unknown	Unknown	Unknown	21504
1/08/2016	7/06/2017	Thigh numbness	Unknown	Unknown	Unknown	Unknown	21497
14/09/2016	19/05/2017	Burning pain	Unknown	Unknown	Unknown	Unknown	21453
15/09/2016	23/05/2017	Seroma	Unknown	Unknown	Unknown	Unknown	21457
20/01/2017	16/05/2017	Inflamed wound	Unknown	Unknown	Unknown	Unknown	21441
31/01/2017	16/05/2017	Haematoma	Unknown	Unknown	Unknown	Unknown	21439
9/02/2017	16/05/2017	Perforation in bowel	Unknown	Unknown	Unknown	Unknown	21440
19/02/2017	7/06/2017	Wound break down	Unknown	Unknown	Unknown	Unknown	21506
24/02/2017	16/05/2017	Haematoma	Unknown	Unknown	Unknown	Unknown	21442
26/02/2017	22/05/2017	Infection	Unknown	Unknown	Unknown	Unknown	21456
1/03/2017	16/05/2017	Extra-peritoneal collection	Unknown	Unknown	Unknown	Unknown	21444
6/03/2017	6/06/2017	Haematoma	Unknown	Unknown	Unknown	Unknown	21496
23/05/2017	21/07/2017	Infected mesh	Right Bard 3DMax Mesh	115321	HUAX0787	Obex Medical Ltd	21767
23/05/2017	21/07/2017	Infected mesh	Left Bard 3DMax Mesh	115311	HUAX0039	Obex Medical Ltd	21768
1/01/2018	7/06/2017	Incisional hernia	Unknown	Unknown	Unknown	Unknown	21505

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.

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. See information on the link below:

www.medsafe.govt.nz/regulatory/devicesnew/9AdverseEvent.asp

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.