Australian Government
Department of Health
Therapeutic Goods Administration

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

Users Medical Device Incident Report *eg Doctors, Nurses, Patients, Public*

What should be reported? A medical device is any material instrument, apparatus, machine, implement, contrivance, implant etc (including any component, part or accessory) which is used in health care and includes in-vitro diagnostics. Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

What should you do with the device? Please keep the device and its associated packaging until you are contacted by the TGA/Medsafe. To send the device please follow the instructions in this link <http://www.tga.gov.au/safety/problem-device-report-user.htm#send>

What happens to your report? The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. The report may also be reported to other Health Authorities. If action is considered necessary it may involve any of the following:

1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, performance or quality.
2. Safety Alert – information relating to the correct use of the device to inform those responsible for the device, or affected by the problem.
3. Report in a TGA News Bulletin (a communication produced by the TGA and distributed in Australia and New Zealand to convey information on medical devices) or other appropriate journal(s).

Medical device manufacturers or suppliers should use: <https://www.tga.gov.au/apps/mdir/MDIRSummary.aspx>

A	**Product Identification**	*Please provide all available details*			Date of Report:	3 May 2019
1.	Brand/Trade Name					
2.	Device Description *(eg Urinary Catheter)*	Transvaginal prolapse surgical mesh				
3.	Device Identification	Model	Serial Number	Batch Number	Lot Number	Software (version)
		IntePro R LPP Y-sling	72404000		771684	
4.	Relevant Dates	Purchase (*Approximate*)	Expiry	If Device is Implantable *(eg pacemaker, venous port etc)* Date of Implant		Date of Explant
				22 May 2012		
5.	Manufacturer's name address & telephone					
6.	Supplier's name address and telephone					

B	**Reporting the Problem**	*Please provide all available details*			
7.	Has the supplier been informed of the problem?	☐ YES ☐ NO	If YES Date Contacted	If YES add contact details Name	Phone / Fax
					( )
8.	Where is the device now?	☐ Place of use ☐ With Reporter ☐ With Supplier ☒ With Patient	Please **Do Not** discard the device or related consumables & packaging	Contact for access to device Name	Phone / Fax
					( )
9.	Is this device supplied sterile?	☒ YES ☐ NO	Is this device reusable?	☐ YES ☒ NO	Is this device single use? ☒ YES ☐ NO

C Problem Description

Please provide all available details
If you do not have enough space please add information onto another sheet of paper or into the body of your email.

10. Add a brief description of the problem. Include what led to, or contributed to the problem. *Please do not provide the name of the patient or health professionals who are not reporting this event.

This is where you explain when you had the device implanted and what happened i.e what side effects do you have, when did they start, how have they affected you.

If you have had the device removed (explanted) - when was it removed and what were the results of any testing.

11. Add a brief description of the consequences or outcome of the problem.

Please add sketches and pictures if necessary and/or available

12. Patient Information *Please do not provide the name of the patient.

Gender	female	Age		Weight (Kg)	65kg

Patient History

D Reporter

Please provide all available details - a report without contact details cannot be processed

13. Do you agree to the TGA or Medsafe (depending on the jurisdiction) providing your name and position / occupation to sponsors and manufacturers?
☐ YES ☒ NO

Name	Position / Occupation
	patient
Department, Institution & Address	Phone
	(00) 00000000
	Fax
	( )
Email	

E Initial Reporter

Please provide all available details - a report without contact details cannot be processed

14.

Name	Position / Occupation
This is where you add your details	patient
Department, Institution & Address	Phone
	( )
	Fax
	( )
Email	

F Feedback

Please provide all available details

15. Who can TGA or Medsafe contact for more information regarding this incident?

☐ Reporter ☒ Initial Reporter ☐ Other Appropriate Person

Name	*Name* Your name here	*Name*	*Phone:* ( ) *Fax:* ( )

G Privacy Information

For general privacy information about TGA, go to <http://www.tga.gov.au/about/website-privacy.htm>

For privacy information about Medsafe, go to <http://www.medsafe.govt.nz/other/siteinfo.asp>

The TGA and/or Medsafe collect personal information in this report to:

- Contact reporters of the problem with the medical device if further information is required.
- Contact suppliers and manufacturers of devices and discuss reported problems with them.

· Check that the same information has not been received multiple times for the same problem with a medical device.

H How to submit Post, Fax or Email your completed form to:

	✉ Post to		🖱 email / internet	🖷 Fax to	☎ Phone
Australian Reporters **TGA**	**Reply Paid 100** Medical Devices IRIS TGA PO Box 100 Woden ACT 2606 AUSTRALIA	**Courier delivery:** TGA 136 Narrabundah Ln, Symonston ACT 2609, AUSTRALIA	iris@tga.gov.au <https://www.tga.gov.au/apps/mdir/udir03.aspx>	**(02) 6203 1713**	**FREE HOTLINE** **1800 809 361**
New Zealand Reporters **MEDSAFE**	✉ Post to		🖱 email	🖷 Fax to	☎ Phone
	Product Safety Team MEDSAFE Ministry of Health Deloitte House 10 Brandon Street (PO Box 5013) Wellington NEW ZEALAND		devices@moh.govt.nz	**(04) 819 6806**	**(04) 819 6800**