MEDICAL DEVICE PATIENT INFORMATION MATERIALS

CLINICAL STAFF EDUCATION

26 NOVEMBER 2021 VERSION 1.1

MEDICAL TECHNOLOGY ASSOCIATION OF AUSTRALIA

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

Desired Outcome

Suppliers	Hospitals	Patients
Provide patient information materials to hospitals	Provide patient information materials to patients	Receive patient information materials

BACKGROUND

- TGA has introduced a new legislation that requires patient information materials to be provided for all implantable medical devices

- Patient information materials consist of:
  - Patient information leaflet (PIL)
  - Patient implant card (PIC)

- Patient information materials assist patients to:
  - Understand the medical device being implanted
  - Have informed consent conversations
  - Report any adverse events with their implanted medical device

- It is the responsibility of the manufacturer/supplier to provide the patient information materials to the hospital

- TGA guidance document on patient information materials - : https://www.tga.gov.au/resource/medical-device-patient-information-leaflets-and-implant-cards

IMPLEMENTATION TIMELINE

- Implementation timeline

	Patient Information Leaflet (PIL)	Patient Information Card (PIC)
Urogynaecological mesh		
New devices	1 Dec 2018	1 Dec 2018
Existing devices	1 Dec 2019	1 Dec 2019
Surgical mesh		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021
Implantable devices (other than those exempted)		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021

- Some hospitals may already be providing patient information materials for mesh and other new devices
- From 1st Dec 2021, as per the regulations, all implantable devices will require patient information materials

IN SCOPE – IMPLANTABLE DEVICES

Implantable and active implantable devices are defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* as follows:

implantable medical device means a medical device (other than an active implantable medical device) that is intended by the manufacturer:

(a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or

(b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or

(c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure.

active implantable medical device or ***AIMD*** means an active medical device, other than an implantable medical device, that is intended by the manufacturer:

(a) either:

(i) to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being; or

(ii) to be, by medical intervention, introduced into a natural orifice in the body of a human being; and

(b) to remain in place after the procedure.

Examples include:

- Hips
- Knees
- Stents
- ICDs
- Pacemakers
- Breast implants

IMPLANTABLE DEVICES EXCLUDED FROM REQUIREMENT

- Sutures
- Staples
- Dental Fillings
- Dental Braces
- Tooth Crowns
- Wedges
- Plates
- Wires
- Pins
- Clips
- Connectors

- Screws

Exempt
Blocking screw
Cap screw
Set screw
Fiducial screw
Set Screw
Pedicle Screw
Laminar Screw

IMPLANTABLE DEVICES EXCLUDED FROM REQUIREMENT

- Similar Items

Exempt	Not exempt
Anchor/suture anchorClamp	Spine Rod
Transverse cross links/cross connectors	Locking rings
Cleat	Intramedullary Nails
Button/cable plug	Interspinous spacer
ICD adaptor	
ICD extender	
ICD Splitter	
Dental Abutment Fracture pins	
Cables	
Cerclage wires	
Fracture pins	
Lead anchoring sleeve	
Laminar hook	
Grip plate	
Occipito-Cervical and Cervical Spinal Plates	
Thoracolumbar and Lumbosacral Spinal and Buttress Plates	
Interspinous Plates	
Bone Cement Plug	
Centraliser	
Pin Plug/Port Plug/Blind Plug	
Lead end cap (rubber)	
Blanking plugs for acetabular screw holes	
Non expandable cage	
Augments	
General (endosseous) dental implant Washer	
Nut	
Bolt	
Screw hole plug Screw-on sleeve	

IMPLANTABLE DEVICES EXCLUDED FROM REQUIREMENT

Exempt	Not Exempt
Eye irrigation solutions	Viscosuipplements for dermal or intra-articular applications
Opthalmic viscoelastic devices (used during surgery 20-30 mins)	Absorbable collagen based material
Distractors (non-implantable)	Hemostatic Matrix
Multi-Lead Trialing Cable for Spinal Cord Stimulators	Absorbable cranial mesh
Tunneling tools	Resorbable Stent
	Silicone sheets & strips
	Bone cement
	Bonewax
	Implantable tissues
	Tape for wound closure
	Pledgets (implanted)
	Staple line reinforcement

LIST OF EXCLUDED ITEMS

- The list of exempt items is based on the latest version of the TGA guidance document – Version 1.6 (November 2021) - : https://www.tga.gov.au/resource/medical-device-patient-information-leaflets-and-implant-cards

- The guidance also provides more detail about the excluded items

- This list **will** change over time and guidance document will be updated

- It is the manufacturer/supplier's responsibility to determine the medical devices that require patient information materials

HOW PICs CAN BE PROVIDED

- Hard copy – can be bulk supplied to the hospital, hand carried by supplier representatives
- Provided with the device within the packaging
- Electronic – with the requirement that the hospitals prints it out as per the supplier's instructions
- Electronic – to be provided to the patient in electronic form

Note:

This is not an exhaustive list, rather the most common ways suppliers intend on providing the PICs. There may be other ways suppliers provide PICs to the hospitals. A single supplier may also use multiple ways to provide the PICs depending on the implant.

SAMPLE CARDS (STRYKER & MEDTRONIC)

Implant Card stryker

? _____

_____

31 _____ / _____ / _____ patientinfo.stryker.com

Stryker Australia Pty Ltd
8 Herbert Street, St Leonards NSW 2065 www.stryker.com

SIDE 1

Symbol Definitions

? Patient Identification

Healthcare Center or Doctor

31 Date of Implant

Patient Information Website

Affix patient label here.

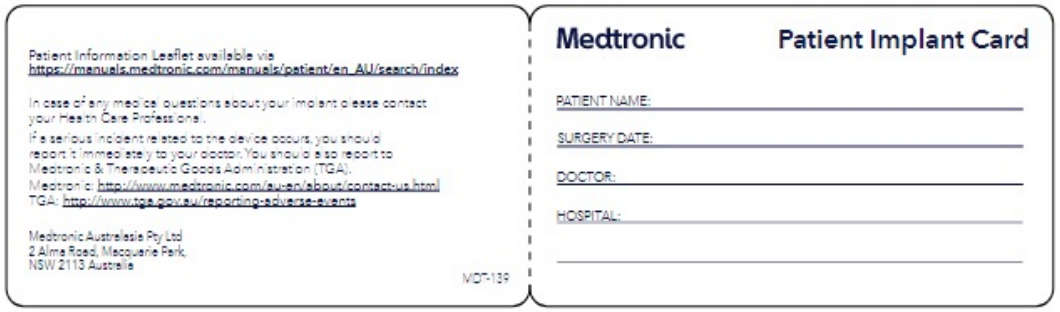
SIDE 2

Affix patient label here.

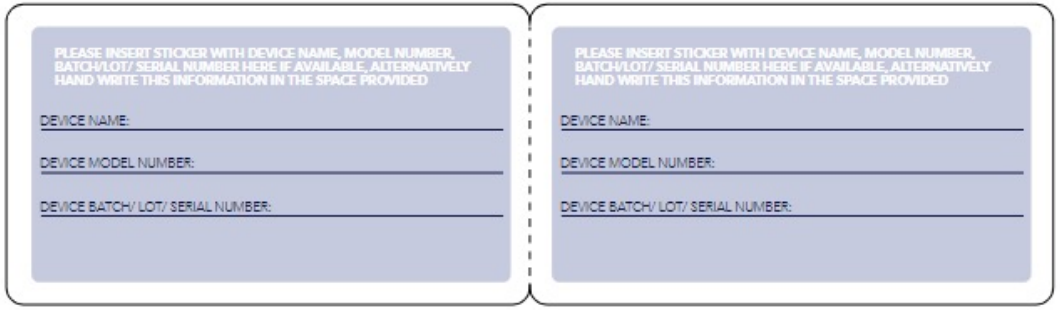
Affix patient label here.

SIDE 3

TOP FRONT



TOP INSIDE



HOW PILs CAN BE PROVIDED

- Hard copy e.g., bulk supplied to hospital
- Provided with the device within the packaging
- Electronic – on the supplier's website with a link provided for access. Supplier to inform hospital where link can be located

Note:

This is not an exhaustive list, rather the most common ways suppliers intend on providing the PILs. There may be other ways suppliers provide PILs to the hospitals. A single supplier may also use multiple ways to provide the PILs depending on the implant.

YOUR ROLE – PICs (IF PROVIDED)

- As devices are implanted during surgery ensure that an implant card is provided/completed for all items that are not exempt. Some cards may already come with the information pre-filled.
- Complete card as instructed by supplier e.g. place sticker, handwrite the information
- Multiple stickers may be placed on a single card or multiple cards provided for each implant system containing more than one component (as per supplier instructions)
- If implants from multiple suppliers are utilised in the one procedure, each supplier should have a separate card with the information for their particular component
- At the end of the procedure all relevant implant cards should be provided to the patient

YOUR ROLE – PILs (IF PROVIDED)

- These may have already been provided where possible prior to surgery by the surgeon
- The device may also have the product leaflet within packaging or provided on supplier/manufacturer website
- If in the packaging, please provide to the patient after surgery
- A link will be provided to this website by the supplier if provided electronically
- A PIL may contain information for an entire system of products rather than requiring an individual PIL for each component. The manufacturer will provide this information

SUPPLY CONCERNS

- There should be no disruption to supply for devices requiring PICs and PILs as TGA has been flexible with how the regulations are met
- Suppliers are required to get consent to supply from TGA for patient information materials that do not meet the regulations
- Suppliers will also provide further specific information to hospitals about provision of patient information materials related to their products – feel free to reach out to them for additional clarification/information if required

NO REQUIREMENT TO RECALL DEVICES WITHOUT PATIENT INFORMATION MATERIALS

- There is no requirement for devices that have already been supplied prior to 1 December 2021 to be recalled from the market if they do not have patient information material

- The TGA considers a medical device to be supplied when it leaves the control of the sponsor. In cases such as loan kits or medical devices that are on consignment, once they are supplied to a hospital they are out of the control of the sponsor/supplier. Therefore, for loan kits and implantable medical devices on consignment prior to 1 December 2021, there is not a requirement for these products to have patient information materials. However, if they return to be in the control of the sponsor, before being supplied to the next hospital, from 1 December 2021, they will require patient information material. How the patient information is provided may vary – i.e.: it can be electronically or in hard copy format and suppliers should confirm with hospitals the most appropriate way to make available the materials

FUTURE

- These regulations and requirements will continue to evolve
- Most of the provision methods here are an interim measure until patient information materials are included in the device packaging
- Future integration with digital health records will also be explored

QUESTIONS

- For non-supplier specific questions, please contact Jasjit Baveja on jbaveja@mtaa.org.au