PATIENT LEAFLET

MUTARS® HIP SYSTEM

VALID FOR: AUSTRALIA

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1. IDENTIFICATIONS

1.1. IDENTIFICATION OF THE MANUFACTURER

MANUFACTURER NAME	implantcast GmbH
ADDRESS	Lueneburger Schanze 26 21614 Buxtehude Germany
TELEPHONE NUMBER	+49 4161 744-0
FAX NUMBER	+49 4161 744-200
WEBSITE	www.implantcast.de

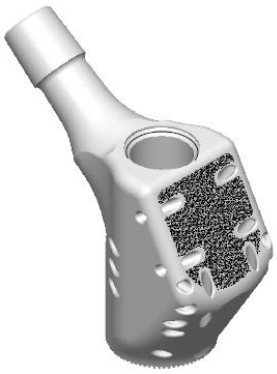
1.2. IDENTIFICATION OF THE SPONSOR (IMPORTER)

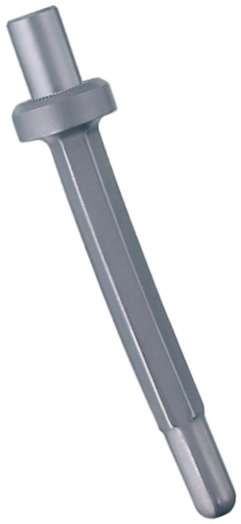
SPONSOR NAME	Lifehealthcare Distribution Pty Ltd
ADDRESS	Level 8/15 Talavera Road North Ryde NSW 2113 Australia
TELEPHONE NUMBER	+61 1800 060 168
WEBSITE	www.lifehealthcare.com.au

1.3. IDENTIFICATION OF THE DEVICE

This patient leaflet is applicable for the following components:

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® prox. femur incl. safety screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57100205 57100207	
MUTARS® prox. femur silver incl. safety screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57100205S 57100207S	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® prox. femur revision incl. safety screw	$TiAl_6V_4$ with EPORE®	57100305 57100307 57100405 57100407	
MUTARS® extension piece	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57722504 57722506 57722508 57722510	
MUTARS® extension piece silver	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57722503S 57722504S 57722506S 57722508S 57722510S	
MUTARS® connecting part incl. screws	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57300100	
MUTARS® connecting part silver incl. screws	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57300100S	
MUTARS® reducer	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57300220 57300230	
MUTARS® reducer silver	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57300220S 57300230S	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® femoral stem cemented	implavit®; CoCrMo acc. to ISO 5832-4	57600011 57600013 57600015 57600017 57601116 57601316 57601516 57601716 57601120 57601320 57601520 57601720 57601124 57601324 57601524 57601724	
MUTARS® femoral stem cemented with HA collar	implavit®; CoCrMo acc. to ISO 5832-4; with TiN coating and implaFix® HA; HA coating acc. to ISO 13779-2	57691211 57691213 57691215 57691217 57691611 57691613 57691615 57691617 57692011 57692013 57692015 57692017 57692411 57692413 57692415 57692417	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® tapered stem cementless	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57602014 57602015 57602016 57602017 57602018 57602019 57602020 57602021 57602022 57602023	
MUTARS® femoral stem cementless HA	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with implaFix® HA; HA coating acc. to ISO 13779-2	57600111 57600012 57600113 57600014 57600115 57600016 57600117 57600018 57600019 57600020	
MUTARS® end piece	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	58600001	
MUTARS® end piece silver	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	58600001S	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® screw	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57921002; 57921004 57921005; 57921006 57921007; 57921008 57921009; 57921010 57921011; 57921012 57921013; 57921014 57921016; 57921018 57921020; 57921022 57921024	
MUTARS® connecting part for diaphyseal implant	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3	57301100 57301120	
MUTARS® connecting part for diaphyseal implant silver	implatan®; $TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57301100S 57301120S	
MUTARS® diaphyseal implant	implavit®; CoCrMo acc. to ISO 5832-4	57301011 57301013 57301015 57301017 57301019	
MUTARS® diaphyseal implant silver	implavit®; CoCrMo acc. to ISO 5832-4; with silver coating	57301013S 57301015S 57301017S 57301019S	
MUTARS® diaphyseal implant TiN	implavit®; CoCrMo acc. to ISO 5832-4; with TiN coating	57301013N 57301015N 57301017N 57301019N	
MUTARS® diaphyseal implant with HA collar	implavit®; CoCrMo acc. to ISO 5832-4; with TiN coating and implaFix® HA; HA coating acc. to ISO 13779-2	57391013 57391015 57391017 57391019	
MUTARS® diaphyseal implant cpTi/HA	implavit®; CoCrMo acc. to ISO 5832-4; with implaFix® Duo; cpTi-coating and HA-coating acc. to ISO 13779-2	57301015HA 57301017HA 57301019HA	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® attachment tube	PET	59000300, 59000310	

No known manufacturing residuals that could pose any health hazard are on the listed devices.

2. INTENDED PURPOSE

The MUTARS® Hip System is the hip portion of the overall MUTARS® System. It is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects.

MUTARS® prox. Femur, MUTARS® prox. Femur silver, and MUTARS® prox. femur revision are femoral components intended to replace the proximal part of the femur in proximal or total femur replacement.

MUTARS® extension piece and MUTARS® extension piece silver are intended for extraosseous length adjustment in the area of the proximal, diaphyseal and distal femur and in the area of the proximal and diaphyseal tibia for bridging of bone defects.

MUTARS® connecting part and MUTARS® connecting part silver are intended for extraosseous length adjustment in the area of the proximal, diaphyseal and distal femur and in the area of the proximal and diaphyseal tibia for bridging of bone defects.

MUTARS® reducer and MUTARS® reducer silver are intended for extraosseous length adjustment in cases of a total femur replacement to enable a connection between the proximal and distal femur replacement.

MUTARS® femoral stem cemented and MUTARS® femoral stem cemented with HA collar are stems for cemented fixation intended for a diaphyseal anchorage in the femur.

MUTARS® femoral stem cementless HA and MUTARS® tapered stem cementless are stems for cementless fixation intended for a diaphyseal anchorage in the femur.

MUTARS® end piece and MUTARS® end piece silver are intended to be used in rare cases of bone tumors and bone metastases, in which no full extremity preserving surgery can be carried out, to prosthetically preserve a terminal femoral or tibial stump.

MUTARS® screws are intended to join components of the MUTARS® hip and knee systems (except the MUTARS® RS components, MUTARS® intramedullary connecting modules, MUTARS® KRI).

The MUTARS® diaphyseal implants are intended for bridging of bone defects in the femoral diaphyseal area and are to be combined with the MUTARS® connecting part for diaphyseal implant. The MUTARS® diaphyseal implants are intended to be used with bone cement.

The MUTARS® connecting part for diaphyseal implant is intended for bridging of bone defects in the femoral diaphyseal area and is to be combined with the MUTARS® diaphyseal implant. It can also replace the proximal femur when combined with the MUTARS® prox. femur component.

The MUTARS® Silver products are silver-coated endoprostheses. The silver-coated surface forms a long-term prophylaxis against colonization with human pathogenic bacteria.

The MUTARS® Attachment Tube is intended to reinforce the soft tissues being attached by sutures to the prosthetic reconstruction.

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3. INDICATIONS

The decision for replacement of the joint should be based on careful evaluation. The indication for this type of surgery should only be made when all other conservative or surgical alternatives are less promising.

Danger of post-operative complications can be limited by careful evaluation of the individual anatomical and load conditions, the condition of the soft tissues and the condition of the bone bed for the implants.

The provision of prostheses is generally indicated only in patients whose skeleton is fully grown.

Before intervention, preoperative examinations should be performed. The examinations depend on the patient’s history.

To re-establish the full anatomical skeletal function, it may be necessary to readjust any traumatized or diseased bone segment, attach it to present fragments or substitute in by implant components.

Primary indication for the use of the MUTARS® systems is after bone resection because of a tumour. In case of primary tumours an extensive resection, as described by Enneking, into the non-diseased area should be possible to ensure adequate surgical treatment of the disease. If this is not possible other treatment options, such as amputation should be considered. The application of the MUTARS® tumour system should not lead to intralasional or marginal and therefore inadequate therapy.

In case of bone metastasis, the indication is related to the physical condition of the patient. If a resected part of the skeleton cannot take the normal anatomical loading and if simple osteosyntheses will not provide sufficient stability, the implantation of a tumour system may help to re-establish the function quickly and to improve the quality of life of the patient. In case of a multiple osseous affection the indication for the use of the MUTARS® system should be limited if a mobilisation of the patient cannot be expected.

Further indications for the use of the MUTARS® systems are massive bone loss such as in Morbus Gorham or for the revision arthroplasty and for the prosthetic treatment in case of fractures, pseudarthrosis and arthrosis. In benign diseases the resection of the bone should be limited, and the prosthesis should be seen as a place holder only.

The surgeon decides which version of prosthesis for the individual patient is used. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone and deformation of the joint.

Other contraindications that could exclude a joint arthroplasty and that may require alternative (surgical) treatments (such as an arthrodesis) remain valid.

SILVER COATING

The indication for the implantation of a silver coated orthopaedic implant should be made carefully. Patients with a weakened immune system caused by bone marrow suppression after chemotherapy or radiotherapy, generally weakened immune system and chronic inflammation and infection may present an increased risk when implanting an orthopaedic implant.

The MUTARS® Silver is for single use only. The MUTARS® Silver is for cementless and cemented use.

MUTARS® ATTACHMENT TUBE

- Proximal Femur Replacement: Reattachment of the gluteals, the m. iliopsoas, the quadriceps muscle. Reconstruction of the joint capsule;
- Total Humerus and Femur Replacement: Reconstruction of the joint capsule of the hip or shoulder, where applicable, reattachment of extensively detached muscles to minimize cavities. In total humerus replacement- reattachment of the m. biceps humeri.

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4. CONTRAINDICATIONS (CONDITIONS IN WHICH THE IMPLANTS SHOULD NOT BE USED)

The longevity of an orthopedic joint replacement device can be reduced by biological aspects, material characteristics and biomechanical factors. Patient selection and indication should be carefully monitored

especially in patients who are overweight, patients with high physical activity levels and patients younger than 60 years of age.

An absolute contraindication is a known allergy to any of the implant materials used. The label on the secondary packaging of each component specifies the material used. Indication for testing, it is strongly recommended to perform an allergy test.

Another absolute contraindication is infection.

The relative contraindications include:

- Anatomic conditions, which preclude or are not expected to maintain an adequate bony support of the implant or do not allow the implantation of a sufficiently large prosthesis.
- Insufficient quantity and quality of bone stock, e.g., as a result of osteoporosis or osteomalacia
- Vascular disease of the affected limb
- Metabolic disorders that can affect a stable anchorage of the implant
- Bone tumors in the implant fixation area
- Neuromuscular diseases that can impair the affected limb
- Lack of patient compliance
- Mental or neurological conditions that affect the ability or willingness of patients to comply with medical instructions, especially during the healing phase
- Obesity

SILBER COATING

MUTARS® components with silver coating should not be used in patients who are sensitive or allergic to silver.

A silver coated implant should not be implanted during pregnancy or planned pregnancy, as the risks for the unborn child were not tested in conjunction with the silver coating. Same applies to patients with impaired blood-brain barrier since the interactions of the silver ions with nerve tissue are not sufficiently known.

Neurological diseases (such as MS or epilepsy) as well as limited liver and kidney functions are also a contraindication for the implantation of silver-coated implants.

MUTARS® ATTACHMENT TUBE

MUTARS® Attachment Tube is contraindicated in cases of:

- Allergy to one of the implant materials. (The label on the secondary packaging of the respective component indicates the materials used. It is strongly recommended to perform an allergy test.)
- Ongoing infections

Furthermore, the contraindications of the respective MUTARS® Tumor and Revision System.

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5. TARGET POPULATIONS

The target group is patients that meet the indications given in the associated Instructions for Use and for whom the implantation of the MUTARS® Hip System is a suitable therapy. The attending medical doctor decides if the product is suitable for the individual patient, and which implant is to be used. This decision depends on several factors, such as the patient's age and weight, bone quality, shape of the bone and deformation of the joint.

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6. PRODUCT DESCRIPTION

The MUTARS® (Modular Universal Tumor and Revision System) is a universal system of tumor and revision prostheses developed in cooperation with Univ.-Prof. Dr. W. Winkelmann and Univ.-Prof. Dr. G. Gosheger, Department of General Orthopaedics and Orthopaedic Oncology at the University Hospital of Münster, Germany. MUTARS® has been in clinical use in Europe since 1992 for the treatment of extensive bone defects of the lower and upper limbs (shoulder, elbow, hip and knee). The system offers the opportunity for functional replacement in case of major osseous defects from tumor excisions, fractures, infections or revisions of failed total joint replacement prostheses. The complete MUTARS® System includes components to treat defects and failed joint replacement prostheses for the humerus, shoulder, ulna, hip joint, femur, knee joint and proximal tibia.

The MUTARS® System offers the possibility of a silver coating for some parts, which has been shown to reduce bacterial colonization on the device surface and, therefore, effectively counteracts infection which is one of the major complications in tumor and revision arthroplasty. Patients who receive tumor prostheses generally have a weakened immune system due to bone marrow depression caused by chemotherapy, radiotherapy and an overall poor immune system. Additionally, compared to primary arthroplasty, in tumor and revision arthroplasty the surgical area is larger, the blood loss greater and the implant has a larger surface, all of which significantly promote the development of infections. When all non-surgical measures, such as the administration of broad-spectrum antibiotics, no longer help to prevent a bacterial infection and there is the risk of an amputation or fatal sepsis, implanting a silver-coated tumor prosthesis is an option. Only non-bone integrating, or non-anchoring parts of the components are silver coated. The coating is located on the outer parts. No taper or other connection is coated.

Optionally, many components are also offered with a TiN coating which reduces the metal ion release and therefore benefits patients which are at risk of adverse allergic reactions to certain metal types and alloys. The TiN coating is applied on the articulating and non-articulating surface of the respective component.

The MUTARS® Hip System is part of the general MUTARS® System. The MUTARS® Hip System is a modular system offering various components that can be combined (with each other) to replace the proximal femur and address major bone defects with various options depending upon the size and location of the defects of each patient.

The MUTARS® Hip System includes extramedullary components (MUTARS® prox. femur, MUTARS® prox. femur revision) intended to replace the proximal part of the femur, components for extraosseous length adjustment (MUTARS® extension pieces, MUTARS® connecting part, and MUTARS® reducer), femoral stems for a diaphyseal anchorage in the femur (MUTARS® femoral stems cementless and cemented), and screws for connecting the components (MUTARS® screws). The MUTARS® end piece is used in rare cases of bone tumors and bone metastases in which no full extremity preserving surgery can be carried out.

The individual components are connected by means of the MUTARS® cylindrical fit and serration connection and a connecting screw (MUTARS® screw).

LEFT: MUTARS® PROX. FEMUR WITH MUTARS® EXTENTION PIECE, MUTARS® FEMORAL STEM CEMENTLESS HA, AND BIPOLAR HEAD.

RIGHT: MUTARS® PROX. FEMUR WITH MUTARS® REDUCER, MUTARS® EXTENTION PIECE, MUTARS® CONNECTING PART, AND MUTARS® KNEE REPLACEMENT

MUTARS® DIAPHYSEAL IMPLANT WITH MUTARS® CONNECTING PART FOR DIAPHYSEAL IMPLANT AND WITH MUTARS® FEMORAL STEM CEMENTED

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7. RESIDUAL RISKS, UNDESIRABLE EFFECTS, WARNINGS AND PRECAUTIONS

The following risk factors may affect the success of joint replacement:

- Nicotine and/or drug abuse
- Alcoholism
- Muscle insufficiency
- Severe deformities, which lead to an impairment of the anchorage, the exact positioning or function of the implant
- Excessive loading of the operated joint by strong physical work and/or inappropriate sports
- Therapies that may affect bone quality

As with all medical interferences, side effects (negative effects) and complications can occur with the implantation of the MUTARS® System.

In the following the most frequent side effects and complications are listed, which can occur in connection with an implantation of the MUTARS® System.

- Dislocation and loosening of the prosthesis

- Tissue reactions to allergies or foreign body reactions to abrasion particles
- Injury of nerves and vessels with temporary or continuing nerve malfunctions
- Wound hematoma and delayed wound healing
- Cardiovascular disturbances, venous thrombosis, and pulmonary embolism
- Acute postoperative wound infections and late infections with possibility of sepsis
- Subluxation or dislocation of the implant. This may cause severe pain and an abnormal positioning.
- Instability
- Periprosthetic fractures. Bone fractures can occur intraoperatively and as a consequence of an implant loosening or due to overload as well as one-sided joint load.
- Separation of modular components
- Wear of articulating components
- Deformities or breakage of an implant
- Fretting and/or corrosion of modular connections
- Metal related pathologies, including Allergy, Metal sensitivity, ARMD (adverse reactions to metal debris), ALVAL (aseptic lymphocyte-dominated vasculitis-associated lesions), Pseudotumors, Metallosis, elevated metal ion concentration in case of using the M-O-M coupling devices
- Allergy, foreign body reactions and tissue reactions due to metal debris
- Heterotopic ossification
- Secondary sign of wear (erosion) can occur on articulation surface of the joint after implantation of a hemi-prosthesis
- Lengthening or shortening of the affected extremity
- Rotation phenomenon, flexion contracture, ligament loosening
- Trochanteric pseudarthrosis: generally, in combination with early weight bearing and/or insufficient fixation after transtrochanteric approach

The manufacturer or its representative should be notified of any complication or adverse event that may have been caused by or contributed to by the implant or the instrumentation.

Complications and / or any unsatisfactory or negative results can also be attributed to an incorrect indication for use, improper patient selection, errors in surgical technique, improper selection of components, and / or concomitant medical conditions. The treatment thereof is the responsibility of the surgeon and neither the manufacturer nor its distributor and/or agent can be held liable for this.

SILVER COATING

The risk factors which can adversely affect the success of the silver coating include loss of efficiency due to incorrect application (e.g., flushing with an antiseptic that contains iodine). Therefore, observance of intra-operative instructions is of particular importance.

Possible adverse effects include allergic reactions and argyria. Argyria is a complication where a too high silver concentration causes silver ions to be deposited in tissues; this can cause an irreversible grey-blue discoloration of the skin. Circulatory disturbances may increase the risk of argyria.

Argyria is not dangerous to health and not linked with tissue damage or functional disorders. However, the discoloration of the skin can cause severe psychological stress for the person affected.

The manufacturer or its representative should be notified of any complication or adverse event that may have been caused by or contributed to by the silver coated implants.

Complications and / or any unsatisfactory or negative results can also be attributed to an incorrect indication for use, improper patient selection, errors in surgical technique, improper selection of components, and / or concomitant medical conditions. The treatment thereof are the responsibility of the surgeon and neither the manufacturer nor its distributor and/or agent can be held liable for this.

MUTARS® ATTACHMENT TUBE

- Post-operative tear on the joint capsule remain
- Failure of the fixation on the prominent rings of the prosthesis
- Dislocation of the implant
- Tear of the attachment tube
- Movement restrictions in the affected knee joint, such as arthrofibrosis, joint stiffness, flexion contracture
- Injury of surrounding blood vessels, soft tissue (such as quadriceps arthropathy, tibial tendon dysfunction, PCL rupture) or nerves with temporary or continuing nerve malfunctions
- Infection (such as acute postoperative wound infections, deep infections with possibility of sepsis, cellulitis (bacterial infection of the skin and tissues underneath the skin))
- Adverse local tissue reaction (ALTR) to foreign body or abrasion particles
- Allergic reactions to the implant materials
- Pain

Warnings:

	*“Do not re-use“*		*„Caution"*
	*“Do not resterilize“*		*„Read the instructions for use"*
	*„Do not use if package is damaged and consult instructions for use"*		*„ Use-by date"*
	*“Contains hazardous substances”*		

8. MAGNETIC RESONANCE COMPATIBILITY

The MUTARS® Hip System has not been evaluated for safety and compatibility in the MR environment. Please tell your doctor or inform healthcare staff if you are asked to undergo any sort of MRI scan, that you have this implant. Scanning a patient who has this device may result in patient injury.

9. POST-OPERATIVE INFORMATION

Post-operative patient care, patient instructions and warnings are of the utmost importance.

The use of an external support of the operated extremity for a limited period, to stimulate healing is recommended.

Active and passive movements of the patient should be monitored.

The post-operative regime should be aimed at the prevention of overloading of the joint and stimulation of the healing process.

Regular monitoring of position and condition of the prosthetic components and the surrounding bone is recommended.

10. PATIENT INFORMATION

The attending medical doctor must inform the patient before surgery about any alternative surgical treatments and about all aspects of the surgery and the implant, including known complications and side-effects and their consequences.

Additionally, the attending medical doctor must inform about the postoperative limitations. Patients must be informed by their surgeon that the results and durability of their implant are related to patient compliance, patient weight and the physical activities.

The patient must be made aware of postoperative limitations including the consequences of overloading of the joint by excessive weight, strong mechanical load on the affected limb, high levels of physical activity, and it must be pointed out to them that they should adapt their lifestyle to these limitations. The patient should be instructed how to adapt the activities accordingly.

The patient must be told that any kind of high-loading sports should be avoided with the joint operated on, and that implants can break or otherwise fail after such excessive loads.

Depending on the situation (e.g., fall), the use of a device with electric drive, such as an e-scooter, can cause the strong mechanical loading/overloading of the affected limb described above.

The patient must be informed that the instructions of the medical doctor for the time after the operation must be strictly followed.

The patient should be told to immediately inform his doctor if he notices unusual changes in the surgical area.

All information provided to the patient should be documented in writing by the operating medical doctor.

Information to be supplied to the patient with an implanted device is available on our website under the following link: https://www.implantcast.de/en/for-patients/

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11. INCIDENT REPORTING

In case of unusual changes in the surgical area your treating physician should be informed.

If you experience any serious problem, incident or malfunction related to your implant, please report this information to the manufacturer or its Australian sponsor via:

Contact information	Manufacturer	Sponsor
Address	implantcast GmbH Lueneburger Schanze 26 21614 Buxtehude Germany	Life Healthcare Pty Ltd Level 8, 15 Talavera Road, North Ryde, NSW 2113
E-Mail	MDVS@implantcast.de	quality@lifehealthcare.com.au
FAX	+49 4161 744 201	+61 2 8114 1599

And also report to the Therapeutic Goods Administration at http://www.tga.gov.au/reporting-problems.

Address:
TGA
GPO Box 100
Woden ACT 2606

For product complaints:
Phone: 1800 809 361

E-mail: iris@health.gov.au