PATIENT LEAFLET

MUTARS® HUMERUS SYSTEM

VALID FOR: AUSTRALIA

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REVISION: 0

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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	
MUTARS® humerus head incl. safety screw	TiAl6V4 acc. to ISO 5832-3	52000000	
MUTARS® humerus head silver incl. safety screw	TiAl6V4 acc. to ISO 5832-3 with silver-coating	52000000S	
MUTARS® humerus cap	TiAl6V4 acc. to ISO 5832-3 with TiN-coating	52100000 52100005 52100010	

COMPONENT	MATERIAL	MODEL NUMBERS	
MUTARS® humerus cap invers TiN	TiAl6V4 acc. to ISO 5832-3 with TiN-coating	52101000 52101005 52101010	
MUTARS® Glenosphere	UHMW-PE acc. to ISO 5834-2	52101002	
glenoid cemented	UHMW-PE acc. to ISO 5834-2	38004005 38004006	
glenoid cementless round	pure titanium (cpTi) acc. to ISO 5832-2 with HA-coating acc. to ISO 13779-2	38004001	
MUTARS® humerus extension piece	TiAl6V4 acc. to ISO 5832-3	52200020 52200040 52200060	
MUTARS® humerus extension piece silver	TiAl6V4 acc. to ISO 5832-3 with silver-coating	52200020S 52200040S 52200060S	
MUTARS® humerus connecting part	TiAl6V4 acc. to ISO 5832-3	52210080	
MUTARS® humerus connecting part silver	TiAl6V4 acc. to ISO 5832-3 with silver-coating	52210080S	
MUTARS® humerus stem cemented	CoCrMo acc. to ISO 5832-4	52400408 52400409 52400410 52400411 52400412	
MUTARS® humerus stem cemented with HA collar	CoCrMo acc. to ISO 5832-4 with TiN-coating and HA coating acc. to ISO 13779-2	52490408 52490409 52490410 52490411 52490412	

COMPONENT	MATERIAL	MODEL NUMBERS	
MUTARS® humerus stem cementless HA	TiAl6V4 acc. to ISO 5832-3 with HA-coating acc. to ISO 13779-2	52400807 52400808 52400809 52400810 52400811 52400812 52400813 52400814 52400815 52400816 52400817	
MUTARS® humerus end piece	TiAl6V4 acc. to ISO 5832-3	52200001	
MUTARS® humerus end piece silver	TiAl6V4 acc. to ISO 5832-3 with silver-coating	52200001S	
MUTARS® humerus reducer piece	TiAl6V4 acc. to ISO 5832-3	52210000 52210100	
MUTARS® humerus reducer piece silver	TiAl6V4 acc. to ISO 5832-3 with silver-coating	52210000S 52210100S	
MUTARS® humerus screw	TiAl6V4 acc. to ISO 5832-3	52300015 52300035 52300055 52300075	
MUTARS® screw for distal humerus	TiAl6V4 acc. to ISO 5832-3	52301815 52301820 52301825 52301830	
MUTARS® distal humerus incl. axle, safety screw and 2 lock screws	TiAl6V4 acc. ISO 5832-3; CoCrMo acc. ISO 5832-12 (bush/axle)	52500000	

COMPONENT	MATERIAL	MODEL NUMBERS	
MUTARS® distal humerus silver incl. axle, safety screw and 2 lock screws	TiAl6V4 acc. ISO 5832-3 with silver-coating; CoCrMo acc. ISO 5832-12 (axle)	52500000S	
MUTARS® distal Humerus M6, 30 mm, incl. axle, covers and safety screw	TiAl6V4 acc. ISO 5832-3; CoCrMo acc. ISO 5832-12 (axle)	52501300	
MUTARS® proximal ulna incl. safety screw	TiAl6V4 acc. ISO 5832-3; CoCrMo acc. ISO 5832-12 (bush)	52500030	
MUTARS® proximal ulna incl. safety screw silver	TiAl6V4 acc. ISO 5832-3 with silver-coating; CoCrMo acc. ISO 5832-12 (bush)	52500030S	
MUTARS® ulnar component cemented	CoCrMo acc. to ISO 5832-4; CoCrMo acc. ISO 5832-12 (bush)	52500070 52500100 52505070 52505100	
MUTARS® ulna anchorage cementless cpTi + HA	TiAl6V4 acc. to ISO 5832-3 with cpTi-coating and HA-coating acc. to ISO 13779-2; CoCrMo acc. ISO 5832-12 (bush)	52501015 52501020	
MUTARS® ulna stop	UHMW-PE acc. to ISO 5834-2	52501100	

COMPONENT	MATERIAL	MODEL NUMBERS	
MUTARS® humerus diaphyseal implant cemented	TiAl6V4 acc. to ISO 5832-3	57311008 57311009	
MUTARS® humerus diaphyseal implant cemented silver	TiAl6V4 acc. to ISO 5832-3 with silver-coating	57311008S 57311009S	
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® Humerus System is the humerus portion of the overall MUTARS® System. It is a modular shoulder and elbow replacement system offering various components that can be combined to replace the shoulder or elbow joint and address major bone defects.

The MUTARS® Humerus Head is a component that is combined with the MUTARS® Humerus Cap or MUTARS® Humerus Cap Inverse intended to replace the proximal part of the humerus or the total humerus.

The MUTARS® Humerus Cap is a cap that is combined with the MUTARS® Humerus Head intended to replace the humeral head.

The MUTARS® Humerus Cap Inverse is a cap that is combined with the MUTARS® Humerus Head intended to replace the humeral head in case of a reverse shoulder prosthesis.

The Glenoid Cementless Round is a glenoid component intended for cementless fixation to replace the natural glenoid by combination with the MUTARS® Glenosphere for a reverse MUTARS® Humerus replacement.

The MUTARS® Glenosphere is intended to replace the glenoid surface in case of a reverse total shoulder replacement.

The Glenoid Cemented is a glenoid component for cemented fixation intended to replace the natural glenoid.

The MUTARS® Humerus Stem Cemented is a stem for cemented or cementless fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.

The MUTARS® Humerus Stem Cementless is a stem for cementless fixation intended for a diaphyseal anchorage of the shoulder or elbow joint replacement in the humerus and ulna respectively.

The MUTARS® Humerus Extension Piece is intended for extraosseous length adjustment in the area of the proximal and distal humerus for the bridging of bone defects in cases where a proximal or distal humerus replacement component is used. The extension piece may also be used when a total humerus replacement, total elbow replacement or proximal ulna replacement component is required.

The MUTARS® Humerus Connecting Part is intended for extraosseous length adjustment in the area of the proximal and distal humerus for the bridging of bone defects in cases where a proximal or distal humerus replacement component is used. The MUTARS® Humerus Connection Part may also be used when a total humerus replacement, total elbow replacement or proximal ulna replacement is required.

The MUTARS® Humerus 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 end piece can serve to prosthetically preserve a terminal humeral or ulnar stump in cases of a part or total humerus replacement, total elbow replacement or proximal ulna replacement.

The MUTARS® Humerus Reducer is intended for extraosseous length adjustment in cases of a total humerus replacement to enable a connection between the MUTARS® Humerus Head and the Distal Humerus.

The MUTARS® Distal Humerus 50mm is a hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement, total elbow replacement or total humerus replacement.

The MUTARS® Distal Humerus 30mm is a hinged elbow joint component intended to replace the distal part of the humerus in a distal humerus replacement or proximal ulna replacement.

The MUTARS® Ulnar Component is a hinged elbow joint component intended to serve as cemented osseous anchorage in the ulna in case of a distal or total humerus replacement.

The MUTARS® Ulna Anchorage is a hinged elbow joint component intended to serve as cementless osseous anchorage in the ulna in case of a distal or total humerus replacement.

MUTARS® Ulna Stop is intended to be used in combination with the MUTARS® Distal Humerus 30mm and 50mm in order to prevent hyperextension of the elbow joint.

The MUTARS® Proximal Ulna is a hinged elbow joint component intended to replace the part of the proximal ulna in a proximal ulna replacement or total elbow replacement.

The MUTARS® Humerus Screw is a screw intended to join components of the MUTARS® Humerus System.
The MUTARS® Screw for Distal Humerus is a screw intended to join components of the MUTARS® Distal Humerus.

The MUTARS® Axle for Distal Humerus is an axle intended to serve as a connection between the ulnar component and the MUTARS® Distal Humerus.

The MUTARS® Humerus Diaphyseal Implant is intended for bridging of bone defects in the humeral diaphyseal area.

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.

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 Humerus Replacement: Refixation of the rotator cuff, the m.deltoideus, m.pectoralis and where applicable the m. biceps humeri. Reconstruction of the joint capsule after intra-or extra-articular resection;
- 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;

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

The longevity of an orthopaedic 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.

The TiNbN coating reduces the ion release from the CoCrMo alloy of the MOM coupling. The coating wears through in the articulating area. For this reason, the treating physician should evaluate the risks and benefits in case of allergy patients.

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

SILVER 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 these instructions for use and for whom the implantation of the MUTARS® Humerus 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 Tumour and Revision System) is a universal system of tumor and revision prostheses developed in co-operation 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. The MUTARS® System 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 a functional replacement in cases of major osseous defects, from tumour excisions, fractures, infections, or revisions of failed total joint replacement prostheses. The full 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.

For the treatment of one of the major complication in tumor and revision arthroplasty the MUTARS® system offers the possibility of a silver coating which provides long-term prophylaxis against the colonisation of pathogenic bacteria and, therefore, effectively counteracts infection.

Patients who receive tumour 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 is a larger surgical area, greater blood loss as well as a larger surface of the implant, which significantly promotes 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 tumour 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.

The MUTARS® Humerus System is the shoulder and elbow portion of the overall MUTARS® System. It is a modular humerus replacement system offering various components that can be combined to replace the shoulder and elbow joint and address major bone defects with various options depending upon the size and location of the defects of each patient. The MUTARS® Humerus System consists of:

- Humerus Head Components
- Humerus Cap / Cap Inverse Components
- Glenoid / Glenosphere Components
- Distal Humerus Components
- Proximal Ulna Components
- Humeral Stems
- Stem Extension Pieces
- Connecting Parts
- Component Connection Fixation Screws
- A Soft Tissue Attachment PET Surgical Mesh Tube

The MUTARS® Humerus System provides modular proximal and distal humerus components as well as proximal ulna components for creating proximal and distal humerus replacements or proximal Ulna replacements respectively. By using the reducer piece total humeral replacements can be achieved. Caps and Glenoid components are used to form hemi shoulder replacement, reverse shoulder replacement or total (anatomical) shoulder replacement as needed.

Modular humeral stems, stem extension pieces, connecting parts, and end piece components are provided for use as needed in individual cases.

A knit polyethylene terephthalate (PET) mesh soft tissue attachment tube is provided for re-attaching soft tissues to the prosthetic reconstruction.

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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 lymphocytedomi-nated vasculitis-associated Lesions), Pseudotumors, Metallosis
- Allergy, foreign body reactions and tissue reactions due to metal debris
- Heterotopic ossification
- Secondary sign of wear can occur on articulation surface of the joint after implantation of a hemiprosthesis (erosion)
- Lengthening or shortening of the affected extremity
- Rotation phenomenon, flexion contracture, ligament loosening

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 are 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.

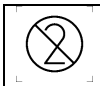
The manufacturer or its representative should be notified of any complication or adverse event that may have been caused by or contributed to by the silver coated implants.

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 joint
- 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:

	*"Single use only"*		*"Attention"*
	*"Do not re-sterilise"*		*"Read the instructions for use"*
	*"Do not use in case of damaged packaging"*		*"Use before date"*
	*"Contains hazardous substances"*		

8. MAGNETIC RESONANCE COMPATIBILITY

The MUTARS® Humerus 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 treating surgeon 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 treating surgeon must inform about the post-operative limitations. Patients should 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 should be made aware of post-operative limitations including the consequences of over-loading of the joint by excessive weight, strong mechanical load on the affected extremity, high levels of physical activities and that the patient should adapt his / her lifestyle to these limitations. The patient should be instructed how to adapt the activities accordingly.

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

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 load / overloading of the affected extremity described above.

The patient should be informed that the instructions of the treating physician for the time after the operation must be strictly followed.

The patient should be noted 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 physician.

Information to be supplied to the patient with an implanted device is available on our homepage under the following link:

https://www.implantcast.de/en/for-patients/

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