PATIENT LEAFLET

EPORE® CONE

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

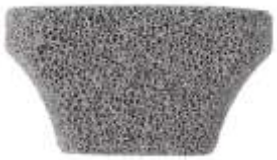
1.2. IDENTIFICATION OF THE SPONSOR (IMPORTER)

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	PICTURE
EPORE® Cone cortical femoral	$TiAl_6V_4$	42174020; 42174025; 42174030; 42174035; 42174040; 42174045; 42174050; 42174055; 42175020; 42175025; 42175030; 42175035; 42175040; 42175045; 42175050; 42175055	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
EPORE® Cone cortical tibial	$TiAl_6V_4$	42170002; 42170003; 42170004; 42170005; 42170022; 42170023; 42170024; 42170025	
EPORE® Cone cortical tibial stepped	$TiAl_6V_4$	42170012; 42170013; 42170014; 42170015; 42170032; 42170033; 42170034; 42170035	
EPORE® Cone met-aphyseal femoral	$TiAl_6V_4$	42170102; 42170103; 42170104; 42170105	
EPORE® Cone met-aphyseal tibial	$TiAl_6V_4$	42171102; 42171103; 42171104; 42171105	

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

2. INTENDED PURPOSE

The EPORE® Cone is intended for use in total knee arthroplasty to fill and replace large bone defects within the proximal tibia and distal femur respectively. It provides a stable support of the femoral and tibial components respectively. It is intended for bone-side cementless and implant-side cemented fixation.

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 metal augments 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 medical history.

Under consideration of these conditions, for the hip joint replacement with the EPORE® Cones in the knee area apply to the following indications:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- post-traumatic osteoarthritis,
- fractures,
- rheumatoid arthritis,
- acetabular bone defects (does not apply to EPORE® Cones)

The following additional indication applies to the EPORE® Cones:

- large bone defects within the proximal tibia and distal femur respectively

The indications of the corresponding endoprosthesis system must also be considered.

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

The longevity of an orthopaedical implant can be reduced by biological aspects, material characteristics and biomechanical factors. Therefore, a careful examination of the indications is recommended in overweight patients, in patients with very high joint loads due to high physical activity as well as in patients younger than 60 years.

The metal augments are 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.

- Physiological or 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.
- Bone tumors (metastases) in the implant fixation area,
- untreated vascular diseases which limit blood supply to the affected limb,
- metabolic disorders that may impair bone formation.

In case of insufficient quantity and quality of bone stock, an alternative prosthetic treatment allowing for sufficient bony fixation should be considered.

The contraindications of the corresponding endoprosthesis system must also be considered.

5. TARGET POPULATIONS

Patients, that meet the indications given in this instruction for use and the implantation of the metal augments is a suitable therapy. The treating surgeon decides whether and which version of the implant is suitable for each patient. 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.

6. PRODUCT DESCRIPTION

6.1. EPORE® Cone Cortical Femoral

FIG. 1: EPORE® CONE CORTICAL FEMORAL – A/P (LEFT) AND M/L (RIGHT)

FIG. 2: EPORE® CONE CORTICAL FEMORAL – PROXIMAL VIEW (ABOVE) AND DISTAL VIEW (BOTTOM)

The outer contour of the EPORE® Cone cortical femoral matches the anatomical femur. The EPORE® Cone cortical femoral implants have an asymmetrical design and are therefore available as left and right configurations. The EPORE® Cone cortical femoral is attached to the femoral component via bone cement.

The EPORE® Cone cortical femoral implant that is selected needs to:

1. fit into the damaged area of the femoral bone without unnecessary removal of viable bone
2. enable the positioning of the femoral component in connection with the offset adapter and the stem
3. ensure the proximal positioning according to the femoral component box and to properly fill the defect, without affecting the intended joint line

6.2. EPORE® Cone Cortical Tibial

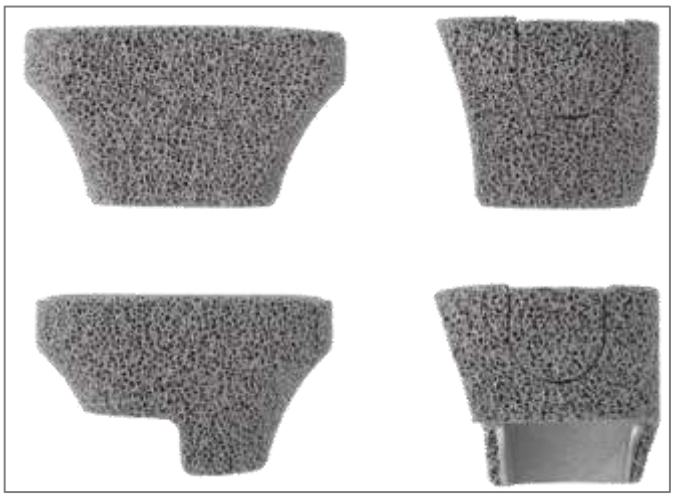

FIG. 3: EPORE® CONE CORTICAL TIBIAL (UPPER ROW) / STEPPED (BOTTOM ROW) – A/P (LEFT) AND M/L (RIGHT)

FIG. 4: EPORE® CONE CORTICAL TIBIAL – DISTAL VIEW (ABOVE) AND PROXIMAL VIEW (BOTTOM)

The outer contour of the EPORE® Cone cortical tibial matches the anatomical tibia. The EPORE® Cone cortical tibial implants have a symmetrical design and therefore can be used for the right and left side. Stepped versions in left and right configurations are also available. There are removable recesses on the lateral and medial side of the tibial cones, which can be broke off in case of fins at the tibial component that is to be combined.

The EPORE® Cones cortical tibial are attached to the tibial component via bone cement. For this reason, the inner contour is massive to avoid penetration of bone cement.

The EPORE® Cone cortical tibial implant that is selected needs to:

1. fit into the damaged area of the tibial bone without unnecessary removal of viable bone
2. enable the positioning of the tibial component in connection with the offset adapter and the stem
3. ensure the proximal positioning according to the tibial component and to properly fill the defect, without affecting the intended joint line.

6.3. EPORE® Cone Metaphyseal Femoral

FIG.5: EPORE® CONE METHAPYSEAL FEMORAL

The EPORE® Cone metaphyseal femoral fills and reconstruct femoral bone deficiencies. The implants have an asymmetric design and can be used for the left and right knee by rotating by 180°.

The implantation of EPORE® Cone metaphyseal femoral is cementless, with a press fit of 0.3 mm. The implants that are used in combination with the EPORE® Cone metaphyseal implants are implanted by the use of bone cement.

The EPORE® Cone metaphyseal femoral implant that is selected needs to:

1. fit into the damaged area of the femoral bone without unnecessary removal of viable bone
2. enable the positioning of the femoral component in connection with the offset adapter and the stem
3. ensure the proximal positioning according to the femoral component and to properly fill the defect, without affecting the intended joint line

6.4. EPORE® Cone Metaphyseal Tibial

FIG.6: EPORE® CONE METAPHYSEAL TIBIAL

The EPORE® Cones metaphyseal tibial fill and reconstruct bone deficiencies within the proximal tibia. The implants have a symmetric design and can be used for left and right knee.

There are medial and lateral recesses for the fins, and posterior for the coupling mechanisms in case of that the cone is combined with a MUTARS® GenuX® MK implant.

The implantation of EPORE® Cones metaphyseal tibial is cementless, with a press fit of 0.3 mm. The implants that are used in combination with the cones metaphyseal implants are implanted by the use of bone cement.

The EPORE® Cone metaphyseal tibial implant that is selected needs to:

1. fit into the damaged area of the tibial bone without unnecessary removal of viable bone
2. enable the positioning of the tibial component in connection with the offset adapter and the stem
3. ensure the proximal positioning according to the tibial component and to properly fill the defect, without affecting the intended joint line

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The materials used for implants are not as resilient as the natural bone structures and joints. They have a limited lifetime. The expected lifetime of the implant generally depends on several factors that can shorten or lengthen it. Some of these factors are the patient's health, activity level and exact implantation of the product.
Under normal conditions the following survival rates (lifetime) are expected. The following values are given in various national endoprostheses registers.

YEARS	SURVIVAL RATE IN % FOR RE-REVISION OF THE KNEE ENDOPROSTHESIS
1	96.53 (95% CI: 96.75 - 96.31)
5	90.94 (95% CI: 91.30 - 90.56)
10	87.89 (95% CI: 84.13 - 82.60)
14	77.90 (95% CI: 82.07 - 72.94)

YEARS	SURVIVAL RATE IN % FOR RE-REVISION OF THE KNEE ENDOPROSTHESIS
	CI: Confidence Interval

Subsequently, minor surgically invasive procedures, such as the replacement of individual components, may be necessary or the implantation of a completely new implant may be necessary. This depends on the reason for the revision.

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7. RESIDUAL RISKS, UNDESIRABLE EFFECTS, WARNINGS AND PRECAUTIONS

The following risk factors may affect the success of the metal augments:

- excessive loading of the operated joint by strong physical work and/or inappropriate sports,
- severe deformities which lead to an impairment of bone fixation or the exact positioning or the function of the implant,
- therapies that may affect bone quality,
- muscle insufficiency,
- neuromuscular diseases of the affected limb,
- conditions that restrict the patient's ability or willingness to comply with medical instructions, especially during the healing process,
- obesity,
- nicotine and/or drug abuse,
- alcoholism,
- previous surgeries on the affected limb,
- diabetes,
- psoriasis,
- intra-articular injection of corticosteroids.

The following procedure-related complications (side-effects) can be associated with orthopaedic surgeries:

- wound hematoma and delayed or impaired wound healing,
- cardiovascular disturbances, venous thrombosis, pulmonary embolism, stroke,
- renal (kidney), urinary, hepatic (liver) or gastrointestinal complications,
- respiratory disorders,

- blood loss requiring transfusions.

As with all surgical interventions side effects (negative effects) and complications can occur with the implantation of the metal augments.

In the following the most frequent side effects and complications are listed which can occur in connection with the implantation of metal augments.

- movement restrictions in the affected knee joint, such as arthrofibrosis, joint stiffness, flexion contracture,
- subluxation, dislocation or instability,
- implant subsidence or early loosening,
- periprosthetic fractures. Bone fractures can occur intraoperatively or due to implant loosening, overload as well as one-sided joint load.
- Heterotopic ossification,
- 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)),
- Inflammation, such as synovitis, bursitis, adhesive capsulitis (adhesion)
- Adverse local tissue reaction (ALTR) to foreign body or abrasion particles
- Allergic reactions to the implant materials
- adverse local tissue reaction (ALTR) to foreign body or abrasion particles,
- allergic reactions to the implant materials,
- separation of modular components,
- deformities or breakage of an implant,
- fretting and/or corrosion of modular connections,
- lengthening or shortening of the affected extremity,
- pain.

The additional indication applies to the EPORE® Cones:

- extensor mechanism failures and injuries of medial structures.

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"*

8. MAGNETIC RESONANCE COMPATIBILITY

The EPORE® Cone 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 is recommended.

Active and passive movements of the operated extremity should be monitored.

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

Regular monitoring of the 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