PATIENT LEAFLET

ACS® KNEE 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
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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
ACS® femoral component cemented	CoCrMo acc. to ISO 5832-4; TiN coated	42003001; 42003002; 42003003; 42003004; 42003005; 42003006; 42003007; 42003008; 42003011; 42003012; 42003013; 42003014; 42003015; 42003016; 42003017; 42003018	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ACS® LD femoral component cemented	CoCrMo acc. to ISO 5832-4	42003801; 42003802; 42003803; 42003804; 42003805; 42003806; 42003807; 42003808; 42003811; 42003812; 42003813; 42003814; 42003815; 42003816; 42003817; 42003818	
ACS® PS femoral component cemented	CoCrMo acc. to ISO 5832-4; TiN coated	42006201; 42006202; 42006203; 42006204; 42006205; 42006206; 42006207; 42006208; 42006211; 42006212; 42006213; 42006214; 42006215; 42006216; 42006217; 42006218	
ACS® LD PS femoral component cemented	CoCrMo acc. to ISO 5832-4	42006101; 42006102; 42006103; 42006104; 42006105; 42006106; 42006107; 42006111; 42006112; 42006113; 42006114; 42006115; 42006116; 42006117	
ACS® LS femoral component cemented	CoCrMo acc. to ISO 5832-4; TiN coated	42007002; 42007003; 42007004; 42007005; 42007006; 42007012; 42007013; 42007014; 42007015; 42007016	
ACS® femoral component cementless pc	CoCrMo acc. to ISO 5832-4; TiN and pc coated	42003101; 42003102; 42003103; 42003104; 42003105; 42003106; 42003107; 42003108; 42003111; 42003112; 42003113; 42003114; 42003115; 42003116; 42003117; 42003118	
ACS® LD femoral component cementless pc	CoCrMo acc. to ISO 5832-4; pc coated	42003901; 42003902; 42003903; 42003904; 42003905; 42003906; 42003908; 42003911; 42003912; 42003913; 42003914; 42003915; 42003916; 42003918; 42210403; 42210404; 42210405; 42210406; 42210413; 42210414; 42210415; 42210416	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ACS® SC femoral component cemented	CoCrMo acc. to ISO 5832-4; TiN coated	42004302; 42004303; 42004304; 42004305; 42004306; 42004308; 42004312; 42004313; 42004314; 42004315; 42004316; 42004318	
ACS® SC femoral component cementless pc	CoCrMo acc. to ISO 5832-4; TiN and pc coated	42004201; 42004202; 42004203; 42004204; 42004205; 42004206; 42004208; 42004211; 42004212; 42004213; 42004214; 42004215; 42004216; 42004218	
ACS® PS femoral component cementless pc	CoCrMo acc. to ISO 5832-4; TiN and pc coated	42006602; 42006603; 42006604; 42006605; 42006606; 42006608; 42006612; 42006613; 42006614; 42006615; 42006616; 42006618	
ACS® femoral component cementless cpTi/TCP	CoCrMo acc. to ISO 5832-4; TiN, cpTi and TCP coated	42003201; 42003202; 42003203; 42003204; 42003205; 42003206; 42003207; 42003208; 42003211; 42003212; 42003213; 42003214; 42003215; 42003216; 42003217; 42003218	
ACS® MB NC PE insert	UHMW-PE acc. to ISO 5834-2; $TiAl_6V_4$ acc. to ISO 5832-3	42027210; 42027212; 42027215; 42027217; 42027310; 42027312; 42027315; 42027317; 42027410; 42027412; 42027415; 42027417; 42027510; 42027512; 42027515; 42027517; 42027610; 42027612; 42027615; 42027617	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ACS® MB PE insert	UHMW-PE acc. to ISO 5834-2; $TiAl_6V_4$ acc. to ISO 5832-3	42026110; 42026112; 42026115; 42026117; 42026120; 42026210; 42026212; 42026215; 42026217; 42026220; 42026310; 42026312; 42026315; 42026317; 42026320; 42026410; 42026412; 42026415; 42026417; 42026420; 42026510; 42026512; 42026515; 42026517; 42026520; 42026610; 42026612; 42026615; 42026617; 42026620	
ACS® MB SC PE insert hyperflex	UHMW-PE acc. to ISO 5834-2; $TiAl_6V_4$ acc. to ISO 5832-3	42029110; 42029112; 42029115; 42029117; 42029120; 42029210; 42029212; 42029215; 42029217; 42029220; 42029310; 42029312; 42029315; 42029317; 42029320; 42029410; 42029412; 42029415; 42029417; 42029420; 42029510; 42029512; 42029515; 42029517; 42029520; 42029610; 42029612; 42029615; 42029617; 42029620	
ACS® MB PE insert DD	UHMW-PE acc. to ISO 5834-2; $TiAl_6V_4$ acc. to ISO 5832-3	42023210; 42023212; 42023215; 42023217; 42023220; 42023310; 42023312; 42023315; 42023317; 42023320; 42023410; 42023412; 42023415; 42023417; 42023420; 42023510; 42023512; 42023515; 42023517; 42023520; 42023610; 42023612; 42023615; 42023617; 42023620	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ACS® MB PS PE insert hyperflex	UHMW-PE acc. to ISO 5834-2; $TiAl_6V_4$ acc. to ISO 5832-3	42028110; 42028112; 42028115; 42028117; 42028120; 42028210; 42028212; 42028215; 42028217; 42028220; 42028310; 42028312; 42028315; 42028317; 42028320; 42028410; 42028412; 42028415; 42028417; 42028420; 42028510; 42028512; 42028515; 42028517; 42028520; 42028610; 42028612; 42028615; 42028617; 42028620	
ACS® FB PE in-sert hyperflex	UHMW-PE acc. to ISO 5834-2	42402210; 42402212; 42402215; 42402217; 42402220; 42402310; 42402312; 42402315; 42402317; 42402320; 42402410; 42402412; 42402415; 42402417; 42402420; 42402510; 42402512; 42402515; 42402517; 42402520; 42402610; 42402612; 42402615; 42402617; 42402620	
ACS® FB PS PE insert hyperflex	UHMW-PE acc. to ISO 5834-2	42401210; 42401212; 42401215; 42401217; 42401220; 42401310; 42401312; 42401315; 42401317; 42401320; 42401410; 42401412; 42401415; 42401417; 42401420; 42401510; 42401512; 42401515; 42401517; 42401520; 42401610; 42401612; 42401615; 42401617; 42401620	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ACS® FB SC PE insert	UHMW-PE acc. to ISO 5834-2	42403210; 42403212; 42403215; 42403217; 42403220; 42403310; 42403312; 42403315; 42403317; 42403320; 42403410; 42403412; 42403415; 42403417; 42403420; 42403510; 42403512; 42403515; 42403517; 42403520; 42403610; 42403612; 42403615; 42403617; 42403620	
ACS® FB PE insert ultra	UHMW-PE acc. to ISO 5834-2	42422210; 42422212; 42422215; 42422217; 42422220; 42422310; 42422312; 42422315; 42422317; 42422320; 42422410; 42422412; 42422415; 42422417; 42422420; 42422510; 42422512; 42422515; 42422517; 42422520; 42422610; 42422612; 42422615; 42422617; 42422620	
ACS® MB tibial component cemented	CoCrMo acc. to ISO 5832-4 TiN coated	42010212; 42010213; 42010214; 42010215; 42010216; 42010217; 42010219	
ACS® LD MB tibial component cemented	CoCrMo acc. to ISO 5832-4	42010822; 42010823; 42010824; 42010825; 42010826; 42010827	
ACS® MB tibial component basic cemented	CoCrMo acc. to ISO 5832-4 TiN coated	42010002; 42010003; 42010004; 42010005; 42010006; 42010007; 42010035	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ACS® MB SC tibial component cemented	CoCrMo acc. to ISO 5832-4 TiN coated	42014002; 42014003; 42014004; 42014005; 42014006	
ACS® FB tibial component cemented incl. plugs	CoCrMo acc. to ISO 5832-4 TiN coated	42010422; 42010423; 42010424; 42010425; 42010426; 42010429; 42010432; 42010433; 42010434; 42010435; 42010436; 42010439	
ACS® LD FB tibial component cemented incl. plugs	CoCrMo acc. to ISO 5832-4	42011002; 42011003; 42011004; 42011005; 42011006; 42011012; 42011013; 42011014; 42011015; 42011016	
ACS® MB tibial component cementless pc	CoCrMo acc. to ISO 5832-4 TiN and pc coated	42013102; 42013103; 42013104; 42013105; 42013106; 42013107; 42013109	
ACS® LD MB tibial component cementless pc	CoCrMo acc. to ISO 5832-4 pc coated	42010902; 42010903; 42010904; 42010905; 42010906; 42010907; 42010909	
ACS® MB tibial component basic cementless	CoCrMo acc. to ISO 5832-4 TiN coated	42010102; 42010103; 42010104; 42010105; 42010106; 42010107; 42010135	
ACS® MB SC tibial component cementless pc	CoCrMo acc. to ISO 5832-4 TiN and pc coated	42014102; 42014103; 42014104; 42014105; 42010106	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ACS® FB tibial component cementless pc incl. extension stem	CoCrMo acc. to ISO 5832-4 TiN and pc coated	42010402; 42010403; 42010404; 42010405; 42010406; 42010409; 42010412; 42010413; 42010414; 42010415; 42010416; 42010419	
ACS® LD FB tibial component cementless incl. extension stem	CoCrMo acc. to ISO 5832-4 pc coated	42010442; 42010443; 42010444; 42010445; 42010446; 42010449; 42010452; 42010453; 42010454; 42010455; 42010456; 42010459	
ACS® MB tibial component cementless cpTi/TCP	CoCrMo acc. to ISO 5832-4 TiN, cpTi and TCP coated	42010202; 42010203; 42010204; 42010205; 42010206; 42010207; 42010209	
ACS® extension stem	$TiAl_6V_4$ acc. to ISO 5832-3 TiN coated	42014025; 42014050; 42014075	
ACS® extension stem male taper	$TiAl_6V_4$ acc. to ISO 5832-3 TiN coated	42014225; 42015235; 42014250	
ACS® stem	$TiAl_6V_4$ acc. to ISO 5832-3	42081210; 42081410; 42081610; 42081810; 42082010; 42082210; 42082015; 42081215; 42082215; 42081415; 42081615; 42081815; 42081220; 42081420; 42081620; 42081820	
ACS® double taper	$TiAl_6V_4$ acc. to ISO 5832-3	42010460; 42010462; 42010464; 42014075	
ACS® MB offset adapter	$TiAl_6V_4$ acc. to ISO 5832-3	42083002; 42083004	
ACS® FB tibial spacer	$TiAl_6V_4$ acc. to ISO 5832-3	42075052; 42075053; 42075054; 42075055; 42075056; 42075059; 42075102; 42075103; 42075104; 42075105; 42075106; 42075109; 42070052; 42070053; 42070054; 42070055; 42070056; 42070059; 42070102; 42070103; 42070104; 42070105; 42070106; 42070109	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
ACS® SC femoral spacer	$TiAl_6V_4$ acc. to ISO 5832-3	42000525; 42000535; 42000545; 42000555; 42000565; 42000585; 42000520; 42000530; 42000540; 42000550; 42000560; 42000580; 42000025; 42000035; 42000045; 42000055; 42000065; 42000085; 42000020; 42000030; 42000040; 42000050; 42000060; 42000080; 42001025; 42001035; 42001045; 42001055; 42001065; 42001085; 42001020; 42001030; 42001040; 42001050; 42001060; 42001080	
ACS® MB SC tibial spacer	$TiAl_6V_4$ acc. to ISO 5832-3	42080052; 42080053; 42080054; 42080055; 42080056; 42080102; 42080103; 42080104; 42080105; 42080106; 42085052; 42085053; 42085054; 42085055; 42085056; 42085102; 42085103; 42085104; 42085105; 42085106	
ACS® rotating patella component cemented	CoCrMo acc. to ISO 5832-4	420300001; 420300002; 420300003; 420300004; 420300005; 420300006	
ACS® rotating patella component cementless pc	CoCrMo acc. to ISO 5832-4	42030101; 42030102; 42030103; 42030104; 42030105; 42030106	
ACS® PE patella cemented	$TiAl_6V_4$ acc. to ISO 5832-3; UHMW-PE acc. to ISO 5834-2	42030326; 42030329; 42030332; 42030335	
EPORE® metaphyseal component femoral for ACS® SC	$TiAl_6V_4$	42075122; 42075123; 42075124; 42075125	
EPORE® metaphyseal component tibial for ACS® FB	$TiAl_6V_4$	42075112; 42075113; 42075114; 42075115	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
EPORE® metaphyseal component tibial + 10mm	$TiAl_6V_4$	58001122; 58001123; 58001124; 58001125; 58001126; 58001133; 58001134; 58001135; 58001136; 58001144; 58001145; 58001146; 58001155; 58001156	
EPORE® metaphyseal component tibial + 5mm	$TiAl_6V_4$	58001522; 58001523; 58001524; 58001525; 58001526; 58001533; 58001534; 58001535; 58001536; 58001544; 58001545; 58001546; 58001555; 58001556	
EPORE® metaphyseal component femo-ral for GenuX® MK	$TiAl_6V_4$	58001022; 58001023; 58001024; 58001025	

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

2. INTENDED PURPOSE

The ACS® Knee System is a total knee replacement system that consists of numerous components intended to resurface the articulating surface of the femur, tibia and patella.

The ACS® Knee System (*standard*) is intended to resurface the knee joint.

The ACS® PS Knee System is intended for the functional replacement of the posterior cruciate ligament in cases of concurrent loss/damage of both cruciate ligaments.

The ACS® SC Knee System is intended for the functional replacement of the posterior cruciate ligament in cases of concurrent loss/damage of both cruciate ligaments and instable collateral ligaments.

The ACS® [LD] MB Tibial Component, ACS® [LD] MB Tibial Component Basic and ACS® [LD] MB SC Tibial Component are tibial mobile-bearing components intended for cemented or cementless fixation to resurface the tibial condyles.

The ACS® [LD] FB Tibial Component and ACS® [LD] FB+ Tibia are tibial fixed-bearing components intended for cemented or cementless fixation to resurface the tibial condyles.

The ACS® [LD] Femoral Component, ACS® [LD] SC Femoral Component and ACS® [LD] PS Femoral Component are femoral components intended for cemented or cementless fixation to resurface the femoral condyles and trochlear groove.

The, ACS® LS Femoral Component is a femoral component intended for cemented fixation to resurface the femoral condyles and trochlear groove.

The ACS® MB PE-Insert, ACS® MB PE-Insert DD, ACS® MB NC PE-Insert, ACS® MB PS PE-Insert Hyperflex and ACS® MB SC PE-Insert Hyperflex are tibial mobile-bearing inserts intended to articulate with a femoral component.
The ACS® FB/FB+ PE-Insert, ACS® FB/FB+ PS PE-Insert Hyperflex, ACS® FB/FB+ PE-Insert Hyperflex, ACS® FB/FB+ PE-Insert Ultra and ACS® FB/FB+ SC PE-Insert are tibial fixed-bearing inserts intended to articulate with a femoral component.

The ACS® PE-Patella and ACS® Patella Anatomic are all-poly patella implants intended for cemented fixation to resurface the natural patella.

The ACS® Rotating Patella Component is a metal-backed patella implant intended for cemented or cementless fixation to resurface the natural patella.

The ACS® MB/FB Tibial Spacer and ACS® MB SC Tibial Spacer are tibial spacers intended for cemented fixation to fill and replace bone defects within the proximal tibia.

The ACS® SC Femoral Spacer is a femoral spacer intended for cemented fixation to fill and replace bone defects within the distal femur.

The ACS® MB Offset Adapter [for MK Stems] and ACS® Double Taper [for MK Stems] are intended to adjust the offset between a tibial or femoral component and a stem.

The ACS® Stem and ACS® [LD] Extension Stem [Male Taper] are stems intended for cemented or cementless fixation to serve as a diaphyseal anchorage in the femur and tibia respectively.

The ACS® Stem HA is a stem intended for cementless fixation to serve as a diaphyseal anchorage in the femur and tibia respectively.

The EPORE® Metaphyseal Component is intended 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. It is intended for bone-side cementless fixation and is connected with the femoral or, respectively, tibial component via screws or mechanical clamping.

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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 ACS® Knee System 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 the ACS® Knee System applies to the following indications:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- post-traumatic osteoarthritis,
- rheumatoid arthritis.

The use of a retro patellar replacement is particularly recommended for the following indications:

- large and thick patella,
- deformed non-conforming patella,
- severe pre-operative pain.

For the EPORE® metaphyseal components the following indication applies:

- bone defects in the metaphyseal area of the distal femur or proximal tibia.

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.

ATTENTION:

The ACS® Femoral Components may only be used in patients with sufficient stability of the knee joint provided by the collateral ligaments. An exception is the ACS® SC Femoral Components, which are indicated for instabilities of the collateral ligaments.

The primary ACS® Femoral Components may only be used in patients, in which the posterior cruciate ligament is intact. An exception are the combinations with the ACS® MB PE-Inserts as well as the ACS® FB/FB+ PE-Inserts Ultra, which can also be used in the loss or defect of the cruciate ligaments.

The ACS® PS Femoral Components are indicated in patients with loss or defect of both cruciate ligaments.

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

The longevity of an orthopaedic 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 ACS® Knee System is contraindicated in cases of:

- Allergy to one of the implant materials. The TiN-coating reduces the release of metal ions, so that there is a relative contraindication for TiN-coated ACS® components in case of known allergy. (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 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.
- 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.

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5. TARGET POPULATIONS

Patients, that meet the indications given in this instruction for use and the implantation of ACS® Knee System 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.

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6. PRODUCT DESCRIPTION

The ACS® Knee System is a total knee replacement system that consists of numerous components intended to resurface the articulating surface of the femur, tibia and patella. Additional components for anchorage in the tibia and femur and anatomical alignment are also available.

The ACS® Knee System is available as a mobile bearing (MB) and fixed bearing (FB) version. Both versions offer the standardized titanium nitride (TiN) coated and non-coated (LD) components. The tibial and femoral components are available in cementless and cemented version.

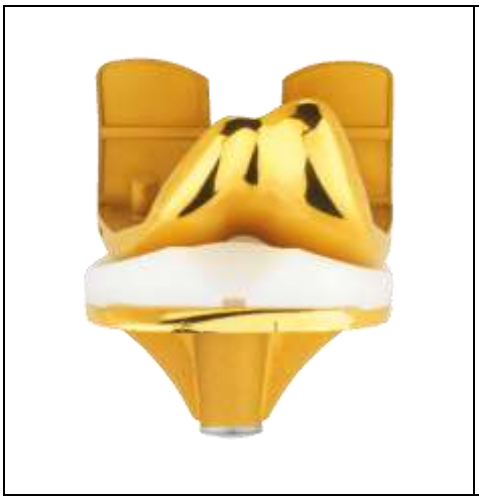

Figure 1: ACS® FB Knee System

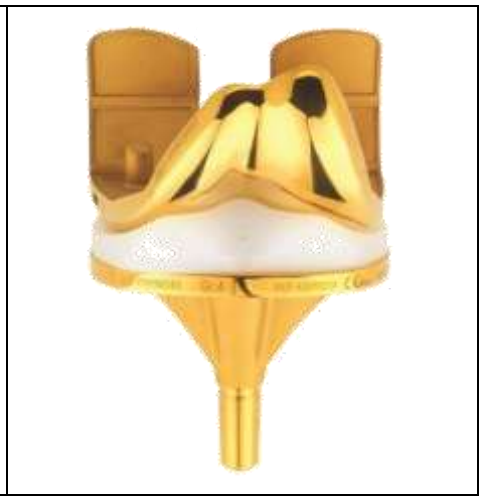

Figure 2: ACS® MB Knee System

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 for the ACS® Knee System. The following values are given in the national endoprostheses register.

YEARS	SURVIVAL RATE IN %			
	CEMENTLESS	CEMENTED		HYBRID
	ACS® FB	ACS® FB	ACS® MB	ACS® FB

1	98.2	98.6	99.2	98.3
3	95.0	97.5	98.1	94.8
5	94.8	96.3	95.5	94.8

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.

7. RESIDUAL RISKS, UNDESIRABLE EFFECTS, WARNINGS AND PRECAUTIONS

The following risk factors may affect the success of the ACS® Knee System:

- 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 disease 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.

The implantation of a cementless tibial component in a treatment with ACS® PS Knee System is not recommended in cases of moderate to severe varus malalignment.

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 ACS® Knee System.

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

- 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 and 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), tissue reactions or foreign body reactions to abrasion particles,
- separation of modular components,
- excessive wear of articulating components,
- deformities or breakage of an implant,
- MRP (metal-related pathology) due to corrosion and/or fretting,
- patella erosion or progressive patellar arthrosis (in case of no patella replacement),
- lengthening or shortening of the affected extremity,
- pain,
- patella baja or alta,
- fabella syndrome.

In case of patella replacement, the following additional complications can occur:

- osteonecrosis of the patella,
- extensor mechanism failures

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 ACS® Knee 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 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/

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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

For product complaints:
Phone: 1800 809 361

Woden ACT 2606

E-mail: iris@health.gov.au