PATIENT LEAFLET

MUTARS® 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
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® GenuX® femoral component cemented TiN	CoCrMo nach ISO 5832-4; with TiN coating	57200310N; 57200320N; 57200330N; 57200315N; 57200325N; 57200335N	
MUTARS® GenuX® femoral component cementless TiN	CoCrMo nach ISO 5832-4; with TiN coating	57200215N; 57200225N; 57200235N; 57200210N; 57200220N; 57200230N	
MUTARS® GenuX® MK femur ce-mented TiN	CoCrMo nach ISO 5832-4; with TiN coating	57200505N; 57200515N; 57200525N; 57200535N; 57200545N; 57200500N; 57200510N; 57200520N; 57200530N; 57200540N	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® dist. femur M-O-M TiN incl. safety screw	CoCrMo acc. to ISO 5832-4; $TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2; with TiN coating	57200045N; 57200040N; 57200047N; 57200042N	
MUTARS® dist. femur M-O-M silver incl. safety screw	CoCrMo acc. to ISO 5832-4; $TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2; with silver coating	57200045S; 57200040S; 57200047S; 57200042S	
MUTARS® dist. femur M-O-M TiN/silver incl. safety screw	CoCrMo acc. to ISO 5832-4; $TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2; with TiN and silver coating	57200045SN; 57200040SN; 57200047SN; 57200042SN	
MUTARS® KRI M-O-M TiN incl. safety screw	CoCrMo acc. to ISO 5832-4; $TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2; with TiN coating	57200043N; 57200048N	 [1]
MUTARS® KRI M-O-M TiN/silver incl. safety screw	CoCrMo acc. to ISO 5832-4; $TiAl_6V_4$ acc. to ISO 5832-3, UHMWPE acc. to ISO 5834-2; with silver coating	57200043SN; 57200048SN	

[1] the TiN coated component is shown as an example

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® tibial plateau M-O-M cementless TiN incl. safety screw + screw for coupling	CoCrMo acc. to ISO 5832-4 with TiN coating	57510203N; 57510200N; 57510205N; 57510210N	 [2]
MUTARS® tibial plateau M-O-M cemented TiN incl. safety screw + screw for coupling	CoCrMo acc. to ISO 5832-4 with TiN coating	57510303N; 57510300N; 57510305N; 57510310N	
MUTARS® tibial plateau M-O-M cemented silver incl. safety screw + screw for coupling	CoCrMo acc. to ISO 5832-4 with silver coating	57510303S; 57510300S; 57510305S; 57510310S	
MUTARS® GenuX® MK tibia cemented TiN incl. counter screw + screw for coupling	CoCrMo acc. to ISO 5832-4 with TiN coating	57510602N; 57510603N; 57510604N; 57510605N; 57510606N	 [2]
MUTARS® modular proximal tibia incl. coupling 15mm	$TiAl_6V_4$ acc. to ISO 5832-3	57500003	
MUTARS® connecting part for mod. prox. tibia	$TiAl_6V_4$ acc. to ISO 5832-3	57500105; 57500125	
MUTARS® GenuX® MK offset adapter	$TiAl_6V_4$ acc. to ISO 5832-3	57510000; 57510002; 57510004; 57510006	
MUTARS® tibial spacer	$TiAl_6V_4$ acc. to ISO 5832-3	58002500; 58003500; 58003505; 58005000; 58005005; 58050500; 58051000; 58051500; 58052000; 58100500; 58101000; 58101500; 58102000	

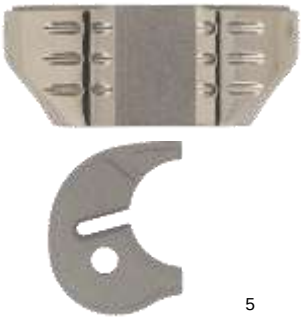
[2] the uncoated component is shown as an example

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® tibial spacer silver	$TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	58002500S; 58003500S; 58003505S; 58005000S; 58005005S; 58050500S; 58051000S; 58051500S; 58052000S; 58100500S; 58101000S; 58101500S; 58102000S	
MUTARS® femoral spacer	$TiAl_6V_4$ acc. to ISO 5832-3	57220530; 57220535; 57220540; 57220545; 57220550; 57220555; 57221030; 57221035; 57221040; 57221045; 57221050; 57221055	 [3]
MUTARS® femoral spacer silver	$TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57220530S; 57220535S; 57220540S; 57220545S; 57220550S; 57220555S; 57221030S; 57221035S; 57221040S; 57221045S; 57221050S; 57221055S	
MUTARS® L-femoral spacer	$TiAl_6V_4$ acc. to ISO 5832-3	57221530; 57221535; 57221540; 57221545; 57221550; 57221555; 57222030; 57222035; 57222040; 57222045; 57222050; 57222055	 [3]
MUTARS® L-femoral spacer silver	$TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57221530S; 57221535S; 57221540S; 57221545S; 57221550S; 57221555S; 57222030S; 57222035S; 57222040S; 57222045S; 57222050S; 57222055S	
MK femoral spacer posterior incl. screw	$TiAl_6V_4$ acc. to ISO 5832-3	57221005; 57222005; 57222505; 57223005; 57224005; 57225005; 57221010; 57222010; 57222510; 57223010; 57224010; 57225010; 57226005, 57226010	 [3]
MK femoral spacer posterior silver incl. screw	$TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57221005S; 57222005S; 57222505S; 57223005S; 57224005S; 57225005S; 57221010S; 57222010S; 57222510S; 57223010S; 57224010S; 57225010S; 57226005S; 57226010S	

[3] the uncoated component is shown as an example

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MK femoral spacer distal incl. screw	$TiAl_6V_4$ acc. to ISO 5832-3	57225105; 57225205; 57225255; 57225305; 57225405; 57225505; 57225605; 57225100; 57225200; 57225250; 57225300; 57225400; 57225500; 57225600; 57220105; 57220205; 57220255; 57220305; 57220405; 57220505; 57220605; 57220100; 57220200; 57220250; 57220300; 57220400; 57220500; 57220600	 [4]
MK femoral spacer distal silver incl. screw	$TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57225105S; 57225205S; 57225255S; 57225305S; 57225405S; 57225505S; 57225605S; 57225100S; 57225200S; 57225250S; 57225300S; 57225400S; 57225500S; 57225600S; 57220105S; 57220205S; 57220255S; 57220305S; 57220405S; 57220505S; 57220605S; 57220100S; 57220200S; 57220250S; 57220300S; 57220400S; 57220500S; 57220600S	

[4] the uncoated component is shown as an example

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MK tibial spacer incl. screw	$TiAl_6V_4$ acc. to ISO 5832-3	57400252; 57400253; 57400254; 57400255; 57400256; 57400352; 57400353; 57400354; 57400355; 57400356; 57400452; 57400453; 57400454; 57400455; 57400456; 57400552; 57400553; 57400554; 57400555; 57400556; 57400652; 57400653; 57400654; 57400655; 57400656; 57400752; 57400753; 57400754; 57400755; 57400756; 57400852; 57400853; 57400854; 57400855; 57400856; 57405052; 57405053; 57405054; 57405055; 57405102; 57405103; 57405104; 57405105; 57405202; 57405203; 57405204; 57405205; 57410052; 57410053; 57410054; 57410055; 57410102; 57410103; 57410104; 57410105; 57410152; 57410153; 57410154; 57410155; 57410202; 57410203; 57410204; 57410205	 [5]

[5] the uncoated component is shown as an example

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MK tibial spacer silver incl. screw	$TiAl_6V_4$ acc. to ISO 5832-3; with silver coating	57400252S; 57400253S; 57400254S; 57400255S; 57400256S; 57400352S; 57400353S; 57400354S; 57400355S; 57400356S; 57400452S; 57400453S; 57400454S; 57400455S; 57400456S; 57400552S; 57400553S; 57400554S; 57400555S; 57400556S; 57400652S; 57400653S; 57400654S; 57400655S; 57400656S; 57400752S; 57400753S; 57400754S; 57400755S; 57400756S; 57400852S; 57400853S; 57400854S; 57400855S; 57400856S; 57405052S; 57405053S; 57405054S; 57405055S; 57405056S; 57405102S; 57405103S; 57405104S; 57405105S; 57405106S; 57405152S; 57405153S; 57405154S; 57405155S; 57405156S; 57405202S; 57405203S; 57405204S; 57405205S; 57405206S; 57410052S; 57410053S; 57410054S; 57410055S; 57410056S; 57410102S; 57410103S; 57410104S; 57410105S; 57410106S; 57410152S; 57410153S; 57410154S; 57410155S; 57410156S; 57410202S; 57410203S; 57410204S; 57410205S; 57410206S	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® tibial stem cementless HA	$TiAl_6V_4$ acc. to ISO 5832-3 with HA-coating acc. to ISO 13779-2	57501512; 57501513; 57501514; 57501515; 57501516; 57501518; 57500212; 57500212; 57500214; 57500215; 57500216	
MUTARS® GenuX® MK stem cementless	$TiAl_6V_4$ acc. to ISO 5832-3	57651212; 57651215; 57651220; 57651225; 57651412; 57651415; 57651420; 57651425; 57651612; 57651615; 57651620; 57651625; 57651812; 57651815; 57651820; 57651825; 57652012; 57652015; 57652020; 57652025; 57652212; 57652215; 57652220; 57652225; 57652412; 57652612; 57652812	 [6]
MUTARS® GenuX® MK stem cementless HA	$TiAl_6V_4$ acc. to ISO 5832-3 with HA-coating acc. to ISO 13779-2	57671212; 57671215; 57671220; 57671225; 57671412; 57671415; 57671420; 57671425; 57671612; 57671615; 57671620; 57671625; 57671812; 57671815; 57671820; 57671825; 57672012; 57672015; 57672020; 57672025; 57672212; 57672215; 57672220; 57672225; 57672412; 57672612; 57672812	

[6] the uncoated component is shown as an example

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® GenuX® MK stem cemented	CoCrMo acc. to ISO 5832-4	57661112; 57661115; 57661120; 57661125; 57661312; 57661315; 57661320; 57661320; 57661512; 57661515; 57661520; 57661525; 57661712; 57661715; 57661720; 57661725; 57661912; 57661915; 57661920; 57661925	
MUTARS® GenuX® MK stem cemented TiN	CoCrMo acc. to ISO 5832-4 with TiN coating	57661112N; 57661115N; 57661120N; 57661125N; 57661312N; 57661315N; 57661320N; 57661325N; 57661512N; 57661515N, 57661520N, 57661525N, 57661712N; 57661715N; 57661720N; 57661725N; 57661912N; 57661915N; 57661920N; 57661925N	
MUTARS® offset adapter	$TiAl_6V_4$ acc. to ISO 5832-3	57510100; 57510125; 57510150; 57510175	
MUTARS® GenuX® stem cementless	$TiAl_6V_4$ acc. to ISO 5832-3 with TCP-coating	57611312; 57611314; 57611316; 57611318; 57611612; 57611614; 57611616; 57611618; 57612012; 57612014; 57612016; 57612018; 57612412; 57612414; 57612416; 57612418	

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® GenuX® stem cemented	CoCrMo acc. to ISO 5832-4	57621311; 57621313; 57621315; 57621317; 57621611; 57621613; 57621615; 57621617; 57622011; 57622013; 57622015; 57622017; 57622411; 57622413; 57622415; 57622417	 [7]
MUTARS® GenuX® stem cemented TiN	CoCrMo acc. to ISO 5832-4 with TiN coating	57621311N; 57621313N; 57621315N; 57621317N; 57621611N; 57621613N; 57621615N; 57621617N; 57622011N; 57622013N; 57622015N; 57622017N; 57622411N; 57622413N; 57622415N; 57622417N	
MUTARS® GenuX® offset stem cementless	$TiAl_6V_4$ acc. to ISO 5832-3 with TCP-coating	57631612; 57631614; 57631616; 57631618; 57632012; 57632014; 57632016; 57632018; 57632412; 57632414; 57632416; 57632418	
MUTARS® GenuX® offset stem cemented	CoCrMo acc. to ISO 5832-4	57641611; 57641613; 57641615; 57641617; 57642011; 57642013; 57642015; 57642017; 57642411; 57642413; 57642415; 57642417	 [7]
MUTARS® GenuX® offset stem cemented TiN	CoCrMo acc. to ISO 5832-4 with TiN coating	57641611N; 57641613N; 57641615N; 57641617N; 57642011N; 57642013N; 57642015N; 57642017N; 57642411N; 57642413N; 57642415N; 57642417N	

[7] the uncoated component is shown as an example

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® tibial stem cemented	CoCrMo acc. to ISO 5832-4 with TiN- or TiN/HA-coating acc. to ISO 13779-2	57500511; 57500513; 57500515	
MUTARS® tibial stem cemented with HA collar	CoCrMo acc. to ISO 5832-4 with TiN/HA-coating acc. to ISO 13779-2	57591211; 57591213; 57591215	
MUTARS® coupling TiNbN	CoCrMo acc. to ISO 5832-12 with TiNbN-coating	57201210N; 57201212N; 57201217N	
MUTARS® patella replacement cemented	UHMW-PE acc. to ISO 5834-2; TiAl6V4 acc. to ISO 5832-3	57201000; 57201001	

[8] the uncoated component is shown as an example

COMPONENT	MATERIAL	MODEL NUMBERS	PICTURE
MUTARS® PE-insert	UHMW-PE acc. to ISO 5834-2	57210000; 57210013; 57210001; 57210002; 57210006	
MUTARS® GenuX® MK MB PE insert	UHMW-PE acc. to ISO 5834-2; TiAl6V4 acc. to ISO 5832-3	57210102; 57210103; 57210104; 57210105; 57210106; 57210132; 57210133; 57210134; 57210135; 57210136; 57210152; 57210153; 57210154; 57210155; 57210156	
MUTARS® GenuX® MK FB PE insert	UHMW-PE acc. to ISO 5834-2; TiAl6V4 acc. to ISO 5832-3	57210202; 57210203; 57210204; 57210205; 57210206; 57210232; 57210233; 57210234; 57210235; 57210236; 57210252; 57210253; 57210254; 57210255; 57210256	
EPORE® metaphyseal component tibial	$TiAl_6V_4$	58001002; 58001003; 58001004; 58001005	
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® PEEK Knee System is a knee portion of the overall MUTARS® System. It is a modular hinge knee replacement system offering various components that can be combined to replace the knee joint and address major bone defects.

The MUTARS® Distal Femur and MUTARS® KRI are femoral components intended to replace the entire distal femur.

The MUTARS® PEEK-OPTIMA® Lock (incl. MUTARS® Locking Piece for PEEK-OPTIMA Lock) is a coupling component intended to connect a femoral to a tibial component to create a coupled joint that replaces the missing ligaments.

The MUTARS® Tibial Plateau Cementless is a tibial monoblock component intended for cementless fixation to resurface the tibial condyles. It includes a stem for the attachment of the prosthesis from the proximal tibia into the diaphysis of the bone.

The MUTARS® Tibial Plateau Cemented is a tibial monoblock component intended for cemented fixation to resurface the tibial condyles. It includes a stem for the attachment of the prosthesis from the proximal tibia into the diaphysis of the bone.

The MUTARS® BioXpand Tibial Plateau is a tibial monoblock component intended for cementless fixation to resurface the tibial condyles. It includes a stem for the attachment of the prosthesis from the proximal tibia into the diaphysis of the bone.

The MUTARS® Tibial Plateau Modular Cementless is a modular tibial component intended for cementless fixation to resurface the tibial condyles.

The MUTARS® Tibial Plateau Modular Cemented is a modular tibial component intended for cemented fixation to resurface the tibial condyles.

The MUTARS® PE-Insert is a tibial fixed-bearing insert intended to articulate with a femoral component.

The MUTARS® Stem for Tibial Plateau Modular Cementless is a stem intended for cemented fixation to serve as a diaphyseal anchorage in the femur and tibia respectively.

The MUTARS® Stem for Tibial Plateau Modular Cemented is a stem intended for cemented fixation to serve as a diaphyseal anchorage in the femur and tibia respectively.

The MUTARS® Patella Replacement is an all-poly patella implant intended for cemented fixation to resurface the natural patella.

The MUTARS® Screw for Tibial Plateau Modular is a screw intended to connect two implant components.

The Counter Screw is a screw intended to secure a screw.

The MUTARS® M-O-M Knee System is a knee portion of the overall MUTARS® System. It is a modular hinge knee replacement system offering various components that can be combined to replace the knee joint and address major bone defects.

The MUTARS® GenuX® Femoral Component Cementless is a femoral component intended for cementless fixation to resurface the femoral condyles and trochlear groove.

The MUTARS® GenuX® Femoral Component Cemented is a femoral component intended for cemented fixation to resurface the femoral condyles and trochlear groove.

The MUTARS® Distal Femur M-O-M and MUTARS® KRI M-O-M are femoral components intended to replace the entire distal femur.

The MUTARS® Coupling is a coupling component intended to connect a femoral to a tibial component to create a coupled joint that replaces the missing ligaments.

The MUTARS® Tibial Plateau M-O-M Cementless is a modular tibial component intended for cementless fixation to resurface the tibial condyles.

The MUTARS® Tibial Plateau M-O-M Cemented is a modular tibial component intended for cemented fixation to resurface the tibial condyles.

The MUTARS® Modular Proximal Tibia is a tibial component intended to replace the entire proximal tibia.

The MUTARS® Femoral Spacer and MUTARS® L-Femoral Spacer are femoral spacer intended for cemented fixation to fill and replace bone defects within the distal femur.

The MUTARS® Tibial Spacer is a tibial spacer intended for cemented fixation to fill and replace bone defects within the proximal tibia.

The MUTARS® GenuX® Stem Cementless, MUTARS® Tibial Stem Cementless and MUTARS® PT Tibial Stem Cementless are stems intended for cementless fixation to serve as a diaphyseal anchorage in the femur and tibia respectively.

The MUTARS® GenuX® Stem Cemented and MUTARS® Tibial Stem Cemented are stems intended for cemented fixation to serve as a diaphyseal anchorage in the femur and tibia respectively.

The MUTARS® Connecting Part for Mod. Prox. Tibia is an adapter intended to connect a tibial component with a stem and/or extension piece.

The MUTARS® screw for femoral spacer, MUTARS® screw for tibial plateau M-O-M, MUTARS® screw for coupling, MUTARS® screw for tibial spacer, MUTARS® counter screw for tibial spacer and MUTARS® screw for KRI are screws intended to connect two implant components.

MUTARS® PE-Plug for Tibial Plateau M-O-M is a plug intended to fill the hole in the tibial component when the tibial stem is not used.

The MUTARS® Peg for Tibial Plateau M-O-M is a peg intended to connect tibial component to the femoral component via MUTARS® PEEK-OPTIMA® Lock.

The MUTARS® MK/HD Knee System is a knee portion of the overall MUTARS® System. It is a modular hinge knee replacement system offering various components that can be combined to replace the knee joint and address major bone defects.

The MUTARS® GenuX® MK Femur [HD] Cementless is a femoral component intended for cementless fixation to resurface the femoral condyles and trochlear groove.

The MUTARS® GenuX® MK Femur [HD] Cemented is a femoral component intended for cemented fixation to resurface the femoral condyles and trochlear groove.

The MUTARS® GenuX® MK Femur Monoblock [HD] is a femoral monoblock component intended for cemented fixation to resurface the femoral condyles and trochlear groove. It includes a stem for the attachment of the prosthesis from the distal femur into the diaphysis of the bone.

The MUTARS® Distal Femur HD and MUTARS® KRI HD are femoral components intended to replace the entire distal femur.

The MUTARS® HD Coupling M-O-M/C-O-M is a coupling component intended to connect a femoral to a tibial component to create a coupled joint that replaces the missing ligaments.

The MUTARS® GenuX® MK Tibia Monoblock is a tibial monoblock component intended for cemented fixation to resurface the tibial condyles. It includes a stem for the attachment of the prosthesis from the proximal tibia into the diaphysis of the bone.

The MUTARS® MK BioXpand Tibial Plateau is a tibial monoblock component intended for cementless fixation to resurface the tibial condyles. It includes a stem for the attachment of the prosthesis from the proximal tibia into the diaphysis of the bone.

The MUTARS® GenuX® MK Tibia Cementless is a modular tibial component intended for cementless fixation to resurface the tibial condyles.

The MUTARS® GenuX® MK Tibia Cemented is a modular tibial component intended for cemented fixation to resurface the tibial condyles.

The MUTARS® MK Proximal Tibia is a tibial component intended to replace the entire proximal tibia.

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

The MK Tibial Spacer is a tibial spacer intended for cemented fixation to fill and replace bone defects within the proximal tibia.

The MUTARS® GenuX® MK MB PE Insert is a tibial mobile-bearing insert intended to articulate with a femoral component.

The MUTARS® GenuX® MK FB PE Insert is a tibial fixed-bearing insert intended to articulate with a femoral component.

The MUTARS® GenuX® MK Stem Cementless is a stem intended for cementless fixation to serve as a diaphyseal anchorage in the femur and tibia respectively.

The MUTARS® GenuX® MK Stem Cemented is a stem intended for cemented fixation to serve as a diaphyseal anchorage in the femur and tibia respectively.

The MUTARS® GenuX® MK Extension Stem is a stem intended for cementless fixation to serve as a diaphyseal anchorage in the femur.

The MUTARS® GenuX® MK Offset Adapter is an adapter intended to adjust the offset between a tibial or femoral component and a stem.

MUTARS® Peg for GenuX® MK Tibia is a peg intended to connect tibial component to the femoral component via MUTARS® PEEK-OPTIMA® Lock.

The MK Screw for Spacer is a screw intended to connect two implant components.

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.

The screw for EPORE® metaphyseal component tibial is a screw intended to connect two implant components.

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 MUTARS® BioXPand tibial plateau and the MUTARS® MK BioXPand tibial plateau are indicated if the defect is primarily located in the femur whereas the tibia is not or only minimally affected.

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.

The following circumstances can cause an increased mechanical load on the coupling mechanism (PEEK-OPTIMA® lock) of the MUTARS® distal femur, which may lead to overloading and possible premature failure.

1) Extra-articular resections

2) Extensive resection of the extension mechanism

3) Other insufficiencies of the muscular system that could lead to insufficient support of the joint.

In these cases the application of the MUTARS® tibial plateau M-O-M is recommended.

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;
- Proximal Femur Replacement: Reattachment of the gluteals, the m.iliopsoas, the quadriceps muscle. Reconstruction of the joint capsule;
- Proximal Tibia Replacement: Reattachment, in particular of the medial and/or lateral gastrocnemius muscle flap and the Lig. Patellae;

- Distal Femur Replacement: Optional after extra-articular resection for augmentation of the knee-flexion;
- 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;
- Arthrodesis: Transfer of the musculus gastrocnemius.

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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

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 these instructions for use and for whom the implantation of the MUTARS® Knee 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 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. 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, frac-

tures, 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® Knee System is part of the general MUTARS® System. It is a modular hinge knee replacement system offering various components that can be combined to replace the knee joint and address major bone defects with various options depending upon the size and location of the defects of each patient.

The complete MUTARS® Knee System consists of the following components:

- distal femoral components
- PE-inserts
- proximal tibial components
- femoral and tibial stems
- extension pieces
- spacers
- component connection fixation screws
- patella replacement
- coupling devices
- offset adapters and
- surgical mesh tube for soft tissue fixation

There are four component systems that together form the MUTARS® Knee System:

- The **MUTARS® "PEEK" Knee System** in which the femoral and tibial components are connected to one another to form a knee joint through the PEEK-OPTIMA® lock.
- The **MUTARS® "M-O-M" Knee System** where the femoral and tibial components are connected to one another to form a knee joint through a metal-on-metal (M-O-M) hinge mechanism.
- The **MUTARS® "MK" Knee System** which is a further development where the intraoperative choice between mobile-bearing and fixed-bearing PE-inserts is given. The biomechanically optimized MUTARS® GenuX® MK coupling allows for 130° flexion. To simplify the system, the same stems are used femoral and tibial in conjunction with the help of offset adapters.
- The **MUTARS® "HD" Knee System** which offers a C-O-M (carbon-on-metal) and M-O-M coupling mechanism based on the MK design.

The components of the three systems are partially combinable (see compatibility in the respective product descriptions).

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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, 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 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
- Trochanteric pseudarthrosis: generally, in combination with early weight bearing and/or unsufficient 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 are the responsibility of the surgeon and neither the manufacturer nor its distributor and/or agent can be held liable for this.

SILBER 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.

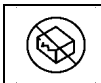
Complications and / or any unsatisfactory or negative results can also be attributed to an incorrect indication for use, improper patient selection, errors in surgical technique, improper selection of components, and / or concomitant medical conditions. The treatment thereof are the responsibility of 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:

	*“Single use only”*		*“Attention”*
	*“Do not re-sterilise”*		*“Read the instructions for use”*

 	*"Do not use in case of damaged packaging"* *"Contains hazardous substances"*		*"Use before date"*

8. MAGNETIC RESONANCE COMPATIBILITY

The MUTARS® 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, 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