SUMMARY TECHNICAL DOCUMENTATION

DEVICE DESCRIPTION – MEGASYSTEM-C®

The following chapter gives an overview of the general information on the product. This includes the history, the used materials and coatings, the foreign country registration, GMDN- and UMDNS-Codes and the intended use of the product. Furthermore indications and contraindications and other general information are described.

1 System

Megasystem-C ®

2 Type of implant

Tumor and Revision Surgery

3 Manufacturer

Waldemar Link GmbH & Co. KG
Barkhausenweg 10
D-22339 Hamburg

4 Device classification

Europe Class III (acc. to MDD 2005/50/EC)

5 Foreign Country Registration

Europe: Certificate No. 7402GB410170801

Design Examination Certificate: 13807GB411170801 (Tumor) & 13805GB411170801 (Knee)

6 GMDN-Code

35666 prosthesis, internal joint, hip

32831 uncoated knee femur prosthesis

33692 Rotating hinged total knee prosthesis

34199 Polyethylene patella prosthesis

48066 Knee stem

48067 Knee wedge

33177 Sleeve femoral extension

33178 Revision uncoated hip femur prosthesis

34190 Uncoated hip femur prosthesis modular

55833 Press-fit hip femur prosthesis, modular

58084 Diaphysis prosthesis

Example of Application – Megasystem-C®

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7 UMDNS-Code

16-095	prosthesis, joint, hip, femoral component
16-096	prosthesis, joint, knee, total

8 Device Description

The design of the modular bone and joint revision system MEGASYSTEM-C® for tumor and revision surgery has been developed in collaboration with Prof. Dr. Capanna of the Centro Traumatologico Ortopedico in Florence.

Due to its high modularity, the system allows partial bone replacements both in the proximal and distal femur in small increments as well as a total replacement of the femur. For the knee joint components, the Endo-Model® SL® Rotational Knee is used in the MEGASYSTEM-C®. The modularity of the system helps to successfully address intraoperative problems.

Observation of biomechanical load and anchoring principles and the application of proven implant components successfully tested over a long period allow utmost safety of the system and thus good prospects for the surgical outcome.

- Maximum intraoperative flexibility using highly modular implant components
- thus reducing costs for true custom-made implants
- System-integrated components compatible with standard implant systems such as the MP® Reconstruction Hip System and Endo-Model® Total Knee Joint Prosthesis System
- Knee joint components based on long-term clinical experience with the Endo-Model®
- Rotational Knee Prosthesis
- Coupling mechanics clinically tested over a long period
- Cementable and cementless stem components
- Length adjustment in 10 mm increments intraoperatively
- Microporous implant surfaces support bone ongrowth
- Easy to handle system-integrated instrumentation

8.1 Materials and coatings

- UHMWPE	acc. to ISO 5834-2 and ASTM F 648
- CoCrMo casting alloy	acc. to ISO 5832-4 and ASTM F 75
- CoCrMo wrought alloy	acc. to ISO 5832-12
- Ti6Al4V casting alloy	acc. to ASTM F 1108
- Ti6Al4V wrought alloy	acc. to ISO 5832-3 and ASTM F 136

8.2 Combination with other medical devices

The Megasystem-C® can be combined with LINK® femoral heads and the Endo- Model® rotational knee system SL.

8.3 History

2001	Megasystem-C® market launch

9 Intended use

The intended use of the modular reconstruction system Megasystem-C® is to reduce or to treat mobility-limiting diseases, fractures or defects of the hip joint, the proximal and distal femur through the proximal tibia which cannot be treated by conservative or osteosynthetic procedures. The

Megasystem-C® is an surgical invasive implant for long term application in the human body. All implants are sterile. Special indications and contraindications are listed in section indications and contraindications.

10 Indication/ Contraindication

General Indications	Knee Rotational	Knee Hinged	Tumor
Mobility-limiting diseases, fractures or defects of the hip joint, the proximal and distal femur through the proximal tibia which cannot be treated by conservative or osteosynthetic procedures.			x
Severe joint diseases with limitation of mobility due to degenerative, rheumatoid or post-traumatic arthrosis or arthritis. Joint fractures which disallow an osteosynthetic reconstruction.	x	x	
Indications	Knee Rotational	Knee Hinged	Tumor
Bone necroses	x	x	
Bicondylar arthrosis by partly damaged collateral ligaments.	x		
Bicondylar arthrosis by completely damaged ligaments and muscular instability.		x	
Revision surgery after hinge knee or rotational knee joint	x	x	
Revision surgery by insufficient / inadequte bone mass	x	x	
Revision arthroplasty due to juxta-articular bone defects			x
Revision of loosened femoral prosthesis components involving extensive bone resorption of the proximal femur and widening of the medullary cavity or marked thinning of proximal femoral cortical bone			x
Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture			x
Deformed proximal femur due to fractures or osteotomies			x
Correction of bone deficiencies, e.g. due to tumors			x
Large post-revision and post-trauma segmental bone defects			x
Oncological and revision surgery from tibial to hip area (in conjunction with Endo-Model® SL Rotational and Hinge Knee Prostheses)			x
Differential Indications			
Arthrosis of patella flange	x	x	
Valgus/Varus deformities <10°	x	x	
Valgus/Varus deformities 10 -15°	x	x	
Valgus/Varus deformities 15 -20°	x	x	
Valgus/Varus deformities 20 -30°		x	

(Absolute) Contraindications			
Acute or chronic infections, local and systemic	x	x	x
Allergies due to (implant) materials	x	x	x
Distinctive muscular, nerve, vascular or other diseases which put the affected limb at risk.	x	x	x
Insufficient / inadequate bone mass which prevents a stable anchor of the prosthesis.	x	x	x
Revision in septic environment			x
Relative Contraindications	Knee Rotational	Knee Hinged	Tumor
Adiposity	x	x	x
Insufficient musculature	x		
Lacking or foreseeable not assured compliance	x	x	x
Foreseeable overload of joint prosthesis	x	x	x

Please note: These indications/contraindications refer to standard cases. The ultimate decision on whether or not an implant is suitable for a patient must be made by the surgeon based on his/her individual analysis and his/her experience.